

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

FORM 8-K/A
(Amendment No. 1)

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 23, 2026

Processa Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-39531
(Commission File Number)

45-1539785
(IRS Employer Identification No.)

601 21st Street, Suite 300
Vero Beach, FL 32960
(Address of principal executive offices, including zip code)

(772) 453-2899
(Registrant’s telephone number, including area code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	PCSA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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. ☐

This Amendment No. 1 on Form 8-K/A (this “Amendment No. 1”) amends the Current Report on Form 8-K filed by Processa Pharmaceuticals, Inc. (the “Company”) with the Securities and Exchange Commission (the “SEC”) on July 29, 2026 (the “Original Filing”), in which the Company reported, among other events, the completion of the acquisition of Vidya Therapeutics, Inc., a Delaware corporation (“Vidya”). This Amendment No. 1 is filed to (i) update the information in Item 9.01(a) of the Original Report to include the audited financial statements of Vidya as of and for the years ended December 31, 2025 and 2024 and the unaudited interim condensed consolidated financial statements of Vidya as of and for the six months ended June 30, 2026 and 2025; and (ii) update the information in Item 9.01(b) of the Original Report to include the unaudited pro forma condensed consolidated financial information of the Company as of and for the six months ended June 30, 2026 and the year ended December 31, 2025. The financial statements have been presented for Vidya, which was the entity that held all of the assets acquired. Additionally, this Amendment No. 1 is filed to incorporate by reference business and risk factor information of Vidya. This Amendment No. 1 does not amend any other item of the Original Report.

Capitalized terms used but not defined herein have the meanings given to them in the Original Report.

In accordance with Rule 12b-15 of the Securities Exchange Act of 1934, as amended, the complete text of Item 9.01 (as amended) is included herein.

Item 8.01. Other Events

The information set forth in the “Business Section of the Company” reflecting the business of the Company following the acquisition of Vidya is attached hereto as Exhibit 99.3 and incorporated herein by reference.

The information regarding the risks associated with the business and operations of the Company following the acquisition of Vidya set forth in the “Risk Factors of the Company” is attached hereto as Exhibit 99.4 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(a) Financial statements of business acquired

The audited financial statements of Vidya as of and for the years ended December 31, 2025 and 2024 and the related notes thereto are attached hereto as Exhibit 99.5 and incorporated herein by reference.

The unaudited interim condensed consolidated financial statements of Vidya as of and for the six months ended June 30, 2026 and 2025 and the related notes thereto are attached hereto as Exhibit 99.6 and incorporated herein by reference.

(b) Pro forma financial information

The unaudited pro forma condensed combined financial information of the Company as of and for the six months ended June 30, 2026 and the year ended December 31, 2025 is attached hereto as Exhibit 99.7 and incorporated herein by reference.

Exhibit Number	Description
2.1*	<u>Agreement and Plan of Merger, dated July 28, 2026, by and among Processa Pharmaceuticals, Inc., Venus Merger Sub I, Inc., Venus Merger Sub II, LLC and Vidya Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-39531), filed with the SEC on July 29, 2026)</u>
3.1	<u>Certificate of Designation of Series A Non-Voting Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-39531), filed with the SEC on July 29, 2026)</u>
10.1*	<u>Form of Securities Purchase Agreement, dated as of July 28, 2026, by and among Processa Pharmaceuticals, Inc. and each investor listed on Exhibit A thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-39531), filed with the SEC on July 29, 2026)</u>
10.2	<u>Form of Registration Rights Agreement, by and among Processa Pharmaceuticals, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-39531), filed with the SEC on July 29, 2026)</u>
23.1	<u>Consent of Cherry Bekaert LLP, Independent Registered Public Accounting Firm</u>
99.1	<u>Press Release issued on July 29, 2026 (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K (File No. 001-39531), filed with the SEC on July 29, 2026)</u>
99.2	<u>Investor Presentation, dated July 29, 2026 (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K (File No. 001-39531), filed with the SEC on July 29, 2026)</u>
99.3	<u>Business Section of the Company</u>
99.4	<u>Risk Factors of the Company</u>
99.5	<u>Audited Financial Statements of Vidya Therapeutics, Inc. as of and for the year ended December 31, 2025 and 2024 and the related notes thereto.</u>
99.6	<u>Unaudited Interim Condensed Consolidated Financial Statements of Vidya Therapeutics, Inc. as of and for the six months ended June 30, 2026 and 2025 and the related notes</u>
99.7	<u>Unaudited Pro Forma Condensed Combined Financial Information of the Company as of and for the six months ended June 30, 2026 and the year ended December 31, 2025</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Certain schedules and attachments have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company agrees to provide, on a supplemental basis, a copy of any omitted schedules and attachments to the Securities and Exchange Commission or its staff upon request.

SIGNATURE

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

Processa Pharmaceuticals, Inc.

Date: October 5, 2026

By: /s/ Russell Skibsted

Name: Russell Skibsted

Title: Chief Financial Officer

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion or incorporation by reference of our report, dated October 5, 2026, relating to the consolidated financial statements of Vidya Therapeutics, Inc. as of and for the years ended December 31, 2025 and 2024, included in this Current Report on Form 8-K/A of Processa Pharmaceuticals, Inc. (the “Company”), in (i) the Company’s Registration Statement on Form S-1 (No. 333-283986 and 333-287997), (ii) the Company’s Registration Statement on Form S-3 (No. 333-279588 and No. 333-254983), and (iii) the Company’s Registration Statement on Form S-8 (No. 333-290456).

/s/ Cherry Bekaert LLP

Waltham, Massachusetts
October 5, 2026

Overview

We are a clinical stage biotechnology company with experienced immunology drug developers seeking to improve and expand treatment options for patients suffering from debilitating autoimmune conditions. On July 28, 2026, we acquired Vidya Therapeutics, Inc. (Vidya) pursuant to the terms of an Agreement and Plan of Merger. The acquisition brought into our pipeline Vidya's lead asset, VT7208, is an orally available, covalent binding, irreversible, central nervous system (CNS) penetrant, Bruton's tyrosine kinase (BTK) inhibitor that was rationally designed to optimize for selectivity, potency, and tolerability. In connection with the acquisition, we received \$200 million in gross proceeds, before deducting placement agent and other offering expenses, from a private placement financing of shares of our non-voting convertible preferred stock from a syndicate of new and existing investors, including Bain Capital Life Sciences, Janus Henderson Investors, RA Capital Management, SilverArc Capital, ADAR1 Capital Management, Cormorant Asset Management, Integral Health Asset Management, Marshall Wace, Octagon Capital, Soleus Capital, a large mutual fund, and other institutional investors. Following the acquisition, our lead product candidate is VT7208.

BTK is critical to human immunity, mediating both adaptive and innate immune responses. Dysregulated BTK signaling has been clinically validated as a therapeutic target across multiple autoimmune diseases and B-cell malignancies. We believe BTK inhibition represents a compelling opportunity in autoimmune disease, offering a potentially differentiated approach across multiple disease indications with significant unmet need that is supported by a substantial body of mechanistic understanding and clinical validation.

The full potential of BTK inhibition in autoimmune diseases has yet to be realized, as previous members of the class have demonstrated limitations that may be inconsistent with the safety, tolerability and pharmacologic profile required for long-term, chronic treatment. Based on initial data, we believe VT7208 is differentiated from existing BTK inhibitors, particularly with respect to its rapid onset of action, potency at low doses and initial tolerability profile. We believe VT7208 has the potential to become a once-daily, orally available BTK inhibitor suitable for chronic treatment of both peripheral and CNS autoimmune diseases.

We are advancing VT7208 in three chronic autoimmune indications: food allergy, chronic spontaneous urticaria (CSU) and multiple sclerosis (MS). We selected these indications based on their significant unmet medical need, strong mechanistic rationale and established clinical precedent for BTK inhibition, alignment with the differentiated profile of VT7208, well-defined regulatory pathways and substantial commercial potential.

Our Pipeline

We are also continuing the development of our legacy pharmaceutical assets, including PCS499

Compound	Indication	Phase 1	Phase 2	Phase 3	Anticipated Next Milestones
VT-7208 (BTKi)	Food Allergy				Phase 2 initiation H2'26 Phase 2 PoC data H2'27
	CSU				Phase 2 initiation H2'26 Phase 2 PoC data H1'28
	MS				Phase 2 initiation H1'27 Phase 2 PoC data H2'28

for the treatment of primary glomerular disease, PCS12852 for the treatment of gastroparesis and constipation disorders and PCS11T for the treatment of lung, pancreatic, ovarian, colorectal, gastric, cervical and other cancers, while evaluating strategic opportunities designed to maximize their clinical and long-term value.

Our Strengths

We believe the attributes of our lead clinical asset, VT7208, together with the experience and capabilities of our team, position us to achieve our principal corporate objective: to build a world-leading immunology company by fully realizing the potential of BTK inhibition in chronic autoimmune disease and establishing a durable, multi-indication franchise around VT7208.

A broad, validated target, uniquely situated within the immune system.

BTK offers a breadth of therapeutic reach that few targets can match due to its positioning at the nexus of the innate and adaptive arms of the immune system where it relays signaling downstream of high-affinity IgE (FcεRI), IgG (FcγRI) and B-cell (BCR) receptors. We believe this unique, critical functionality in adaptive immune cells that make autoantibodies and innate immune cells that respond to autoantibodies coupled with its ability to act in both the periphery and CNS offers the potential for disease modification across numerous autoimmune conditions.

VT7208, a potent, specific and durable oral BTK inhibitor

In preclinical studies, VT7208 displayed high selectivity and rapid, potent and durable peripheral and CNS BTK inactivation. VT7208 had strong activity across peripheral and CNS-relevant disease models where pathology is driven by FcR signaling and B cells, including models of arthritis, CNS inflammation and multiple sclerosis. In Phase 1 studies, VT7208 demonstrated near-complete target occupancy within hours, and therapeutic durability beyond 48 hours when administered at our lowest studied dose of 5 mg.

VT7208's initial liver-safety profile appears consistent with needs of chronic use

VT7208 is designed to achieve durable peripheral and CNS BTK inhibition without the high systemic exposure, or broad off-target pharmacology that has often led to liver-safety issues in the BTKi class. At a projected 10 mg QD dose in our Phase 1 trial, VT7208 had an FDA drug-induced liver injury (DILI)-risk algorithm score of 2.1, which we believe supports a low predicted DILI-risk classification (0-3 range). This starting profile was further augmented by initial patient data from our Phase 1 studies, as no dose-limiting toxicities, serious adverse events, or treatment-related discontinuations were observed.

Multiple large market opportunities

We are advancing VT7208 across three indications of significant unmet need and substantial size, food allergies, CSU and MS, which we believe may provide us with several independent opportunities to generate value from VT7208.

An efficient path to clinical proof of concept across indications

Each of our programs is designed to establish clinical proof of concept via precedented, near-term biomarker or challenge endpoints with the potential to generate data in a short period of time. Pursued in parallel, we believe these program designs offer a capital-efficient path to establishing human validation of VT7208's differentiated profile across a portfolio of indications.

An experienced immunology team, led by a proven founder

Our team, which worked collectively to identify and optimize VT7208, has broad experience across autoimmune drug discovery, formulation and development anchored by our founder, Sheila Gujrathi, M.D., who led the clinical development of ocrelizumab (Ocrevus®), the current standard of care in relapsing MS, during her tenure at Roche Pharmaceuticals.

Our Strategy

Our core strategy is to broadly and efficiently validate the potentially differentiated profile of VT7208 by generating initial clinical data across three distinct indications. If successful, we believe this strategy may position our CSU and food allergy programs to enter potentially pivotal studies in the near term and could allow our MS program to capture the full breadth of VT7208's opportunity in each disease subtype over time. The key elements of our strategy include:

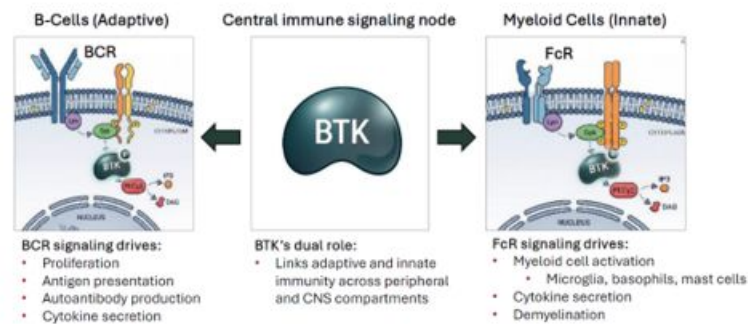
- *Establishing human proof of concept across multiple indications*
- *Designing efficient late-stage trials in food allergy and CSU*
- *Maximizing VT7208's potential breadth in all forms of MS*
- *Leveraging near-term value creation to expand the franchise into other indications*

Our Target:

Bruton's Tyrosine Kinase (BTK): A Dual-Acting Immunomodulatory Node

BTK is an intracellular signaling enzyme that occupies a distinctive position in human immunity. Its activity impacts both the innate and the adaptive arms of the immune system where BTK signaling activates cells whose dysregulation underlies the pathology of many antibody-mediated autoimmune diseases. On the innate side, BTK relays signal downstream of Fc receptors, most notably FcεR1 and FcγR1 on mast cells and basophils that drive the release of histamine, cytokines and other mediators of allergic and inflammatory responses. On the adaptive side, BTK is an essential node in the B cell receptor (BCR) signaling cascade, governing B-cell activation, proliferation and survival and the production of autoantibodies and pro-inflammatory cytokines. Though BTK is expressed in B cells and cells of the myeloid lineage including CNS-resident microglia, it is absent from T cells and antibody-secreting plasma cells. This expression pattern underlies BTK's therapeutic appeal by positioning the enzyme at the intersection of the two immune arms whose interplay drives antibody-mediated disease, while leaving important categories of immune cells untouched.

Importantly, BTK inhibition modulates pathogenic signaling without depleting immune-cell populations further distinguishing it from other autoimmune drug classes which target B cells, as illustrated below.



BTK Inhibitors (BTKi): Clinical Validation in Cancer, Unrealized Potential in Immunology

The first regulatory approval for the BTK inhibitor class was the November 2013 FDA approval of ibrutinib, known commercially as Imbruvica®, for the treatment of mantle cell lymphoma. This first approval was followed by multiple subsequent approvals for both ibrutinib and other members of the class across a range of B-cell cancers. Based on the ability to durably interrupt B cell signaling driving proliferation, a compelling scientific rationale was made for extending the development of BTK inhibitors into antibody-mediated autoimmune diseases.

Clinical efficacy of BTK inhibitors has been demonstrated in several autoimmune diseases; however, this has been slow to translate into regulatory approvals due to challenging risk/benefit profiles. In chronic autoimmune disease, where therapies typically treat non-fatal conditions and may be taken for decades, the bar for acceptable tolerability is far higher than in cancer, where greater toxicity is tolerated in exchange for extending survival. As a result, several members of the BTK inhibitor class have seen their development plans in immunology either halted or impeded by tolerability limitations.

The defining safety concern associated with the BTK inhibitor class in autoimmune disease has been hepatotoxicity. Evobrutinib and fenebrutinib were each placed on partial clinical hold following cases of liver-enzyme elevation, and the development of tolebrutinib, despite an EMA approval in progressive MS, has likewise been impacted by hepatic-safety findings. We believe these hepatic liabilities are the principal reason the substantial potential of BTK inhibition in immunologic diseases has not been fully realized. For a molecule to meet the safety requirements for chronic, long-term use and succeed in the autoimmune arena, it must not only have best-in-class efficacy benefits but also be less impactful on the liver. Creating a BTKi that could meet those dual objectives guided our discovery efforts and rational design of VT7208.

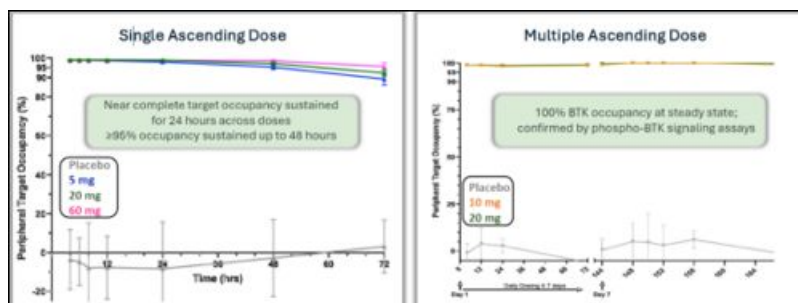
Our Solution: VT7208, a differentiated oral BTK inhibitor

Our development of VT7208 began with its identification from amongst a library of potential candidates as we recognized that its baseline qualities were a promising starting point for an immunology-focused BTK inhibitor. We then further augmented those properties by utilizing rational drug design to optimize the molecule for potency, selectivity, metabolic stability and CNS-penetration to create the overall therapeutic profile we believe has the potential to maximize VT7208’s likelihood of clinical success: rapid onset and persistence of robust target occupancy in periphery and CNS from a low dose that minimizes systemic drug burden. This therapeutic profile is illustrated below. Based on data from the studies we have conducted to date, we believe that VT7208 has established initial evidence of differentiation across these key domains.



Rapid onset, robust, long duration effects from a low dose

At the lowest dose tested in our Phase 1 single-ascending-dose (SAD) study, which was a single 5mg oral dose of VT7208, greater than 95% BTK target occupancy was achieved at the earliest timepoint assessed, four hours, which rose to greater than 99%, and was sustained above 95% for approximately 48 hours post-dose. This profile of rapid, near-complete and durable target occupancy at low, once-daily doses was confirmed in our multiple-ascending-dose (MAD) cohorts where a 10 mg dose achieved 100% target occupancy and signaling inhibition. These results are illustrated below. We believe rapid onset and durable, around-the-clock target coverage from a low once-daily dose are directly relevant to chronic autoimmune disease, where consistent suppression of pathogenic signaling and simple dosing are central to real-world clinical effectiveness and patient satisfaction.

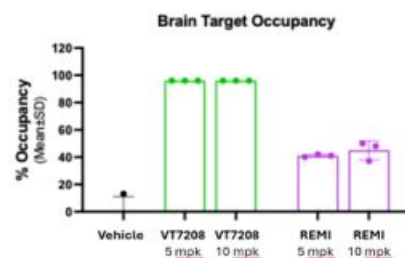
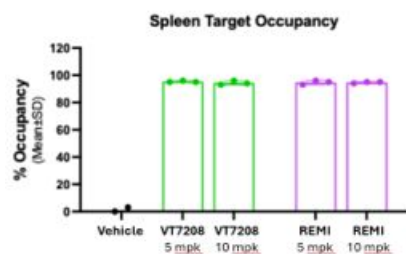


CNS penetration

The ability to reach the CNS at meaningful, sustained concentrations is a prerequisite for addressing the brain neuroinflammation that drives disability progression in MS. Therefore, to establish VT7208's ability to achieve CNS penetration, we have conducted multiple preclinical studies where VT7208 levels could be measured in the brains of animal models and be compared head-to-head with the CNS penetration achieved by other BTKi. In addition, we also measured VT7208 levels in the cerebral spinal fluid (CSF) of the participants in our Phase 1 trial. In the preclinical studies, VT7208 exhibited greater levels of CNS penetration than either tolebrutinib or remibrutinib, two leading BTKi that are either being studied or have been approved in autoimmune indications. Further, in the Phase 1 trial, we observed CNS penetration data for VT7208 consistent with our preclinical studies.

Preclinical mouse target occupancy in the brain

In preclinical studies in naïve mice with an intact blood-brain barrier, which may not be predictive of pharmacologic activity in humans and should be interpreted with caution, VT7208 demonstrated substantially greater BTK target occupancy in the brain than tolebrutinib or remibrutinib administered at the same dose in the two separate head-to-head studies. As depicted below, at steady state, VT7208 achieved approximately 95% brain BTK target occupancy at both 5 mg/kg and 10 mg/kg, compared with approximately 40% and 45%, respectively, for remibrutinib and 66% and 96% for tolebrutinib. In contrast, all three BTK inhibitors achieved approximately 95% BTK target occupancy in the spleen at these doses. We believe the substantially higher brain target occupancy observed with VT7208, despite comparable peripheral target occupancy, provides preclinical evidence of its potential to achieve greater pharmacologic activity within the CNS.

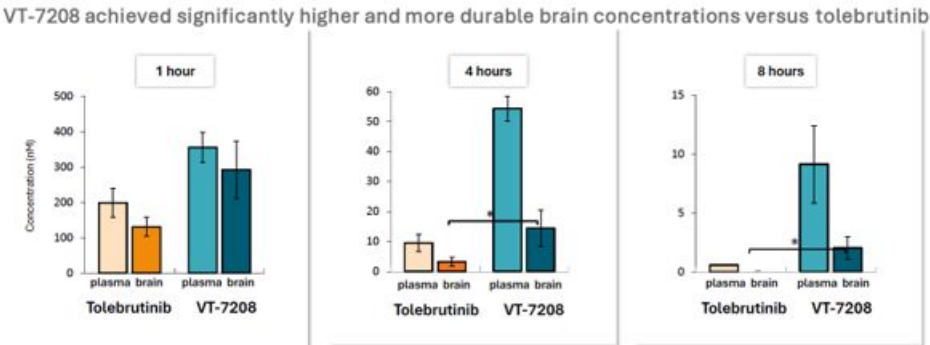


	Dose	Tolebrutinib*	VT-7208*
Mouse spleen Target Occupancy	5 mg/kg	95%	95%
Mouse Brain Target Occupancy		66%	91%
Mouse spleen Target Occupancy	10 mg/kg ^{\$}	95%	95%
Mouse Brain Target Occupancy		96%	99%
*oral dose x 3 days, occupancy determined 1 hour after last dose			
\$10 mg/kg dose is similar to 50 mg human dose by allometric scaling			

	Dose	Remibrutinib*	VT-7208*
Mouse spleen Target Occupancy	5 mg/kg	95%	95%
Mouse Brain Target Occupancy		41%	96%
Mouse spleen Target Occupancy	10 mg/kg [§]	95%	95%
Mouse Brain Target Occupancy		45%	97%
*oral dose x 3 days, occupancy determined 1 hour after last dose			
§10 mg/kg dose is similar to 50 mg human dose by allometric scaling			

Preclinical NHP brain exposure study vs tolebrutinib

VT-7208 demonstrated higher and more sustained brain exposure than tolebrutinib in a head-to-head preclinical study. At one hour following administration, VT-7208 achieved higher concentrations in both plasma and brain relative to tolebrutinib. At four and eight hours, the difference in brain exposure was more pronounced, with VT-7208 maintaining measurable brain concentrations while tolebrutinib concentrations declined substantially and were minimal by eight hours. The higher brain concentrations of VT-7208 relative to tolebrutinib at the later time points were statistically significant. We believe these results demonstrate the ability of VT-7208 to penetrate the blood-brain barrier and maintain exposure in the brain and, together with its BTK potency and target occupancy profile, support the potential of VT-7208 to provide sustained BTK inhibition within the CNS. These results are illustrated below. Because these findings were generated in a preclinical model, they may not be predictive of CNS exposure or pharmacologic activity in humans, and these comparisons should be interpreted with caution.



(nM)	Time post dose	Tolebrutinib	VT-7208
NHP Plasma	1 hr	198	355
NHP Brain		130	292
NHP Plasma	4 hr	9.6	54.2
NHP Brain		3.2	14.4
NHP Plasma	8 hr	0.6	9.1
NHP Brain		0	2.0

VT7208 CSF concentration levels in phase 1 trial participants

Based on human pharmacokinetic data in our Phase 1 trial, a 10 mg once-daily dose of VT-7208 resulted in a CSF concentration of approximately 2 nM, compared with an IC₅₀ of 0.26 nM for inhibition of TNF-α production in a human microglial assay, representing approximately 7.7-fold coverage of the microglial IC₅₀. We believe these data support the potential for VT7208 to achieve pharmacologically relevant CNS exposure at a relatively low projected clinical dose.

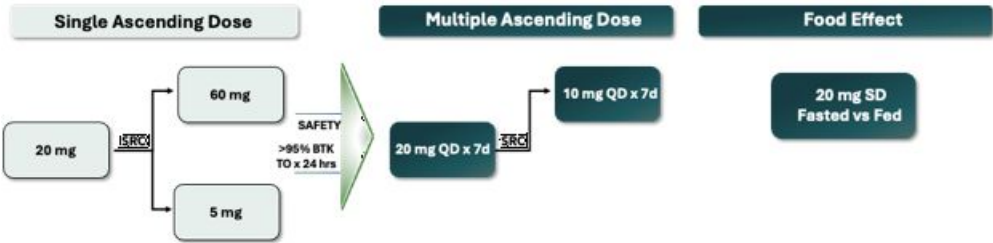
Reduced Hepatotoxicity Risk

Based on our understanding of the underlying hepatic safety concerns associated with the BTKi class, we designed VT7208 to minimize its potential metabolic burden by using a butynamide warhead in contrast to most current clinical and commercial stage BTK inhibitors, which use an inherently more reactive acrylamide warhead. We believe the properties of a butynamide warhead are more consistent with the requirements of a chronically administered drug due to its less promiscuous binding and lower intrinsic metabolite reactivity. To date, VT7208 has demonstrated a balanced profile and low intrinsic off-target reactivity which reduces the formation of reactive metabolites that can contribute to idiosyncratic toxicity and are associated with greater immune-mediated drug induced liver injury (DILI) risk. In preclinical studies, VT7208 showed minimal glutathione (GSH) adduct formation (~1% of the parent compound), a key determinant of reactive metabolite risk that is associated with DILI and produced FDA drug-induced liver injury (DILI)-risk algorithm score of 2.1 which placed it in the low-risk classification (0-3 range).

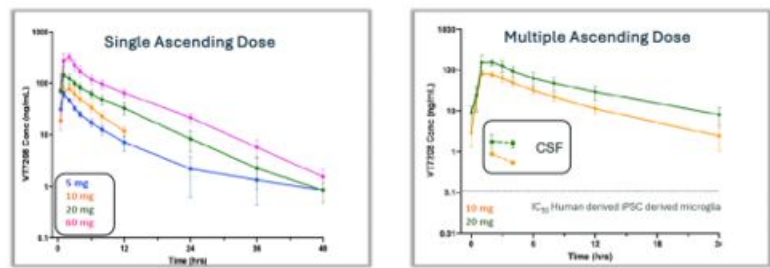
We believe these properties coupled with the low therapeutic doses we have established, starting at 5 mg, may increase our chances of achieving our objective of optimizing VT7208’s tolerability for chronic use. This potential is best represented by the wide therapeutic window that we have observed for VT7208, as measured by the more than 50-fold margin between therapeutic doses and the lowest no observed adverse-effect dose level (NOAEL in dogs considered the most sensitive species) established in our GLP toxicity studies.

Phase 1 Trial

As depicted below, our first human study of VT7208 was a combined single ascending dose (SAD), and multiple ascending dose (MAD), Phase 1 study at doses ranging from 5 mg to 60 mg. The effect of food was examined in a separate food effect cohort. The study included 24 healthy volunteers, 8 per study arm. In the fasting arm of the SAD study and the MAD study, participants were randomized 6:2 to the treatment and placebo arms, while in the fed cohort of the SAD study, all 8 participants received only VT7208. The trial design is illustrated below.



The primary objectives of the trial were the establishment of VT7208’s safety, tolerability, and pharmacokinetic profiles, while the secondary endpoints assessed BTK target engagement and impact on certain translational biomarkers.



As depicted above and below, results from the completed Phase 1 SAD and MAD studies demonstrated that VT7208 exhibited a predictable PK profile with nearly dose proportional exposures across all evaluated dosage levels and was also generally well tolerated. Across all dosage levels, there were no dose-limiting toxicities observed, no serious adverse events reported, no treatment-related discontinuations, and no liver-safety signal or bleeding-related events observed. There was no clinically meaningful food effect observed as VT7208’s PK and tolerability profiles were consistent in both fasted and fed states. These findings are depicted below.

Parameter	SAD			Food Cohort	MAD (QDx7)	
	5 mg	20 mg	60 mg	20 mg	10 mg	20 mg
SAEs	0/6	0/6	0/6	0/8	0/6	0/6
Grade 3 or higher	0/6	0/6	0/6	0/8	0/6	1/6 Blood draw site pain
Related AEs	0/6	1/6 Headache (G1)	0/6	1/8 Headache (G1)	0/6	0/6
CS lab abnormalities	0/6	0/6	0/6	0/5*	0/6	0/6
CS vital sign/ECG abnormalities	0/6	0/6	0/6	0/8	0/6	0/6

6:2 per cohort; food cohort 8 VT-7208
CS – Clinically Significant

*Data entry ongoing

Preclinical and Phase 1 data collectively suggests that VT7208 has a differentiated profile within the BTK inhibitor class

While representing early-stage findings in a limited number of subjects, we believe the collective preclinical data we have generated when combined with the results of our Phase 1 trial provide compelling evidence of VT7208’s potential as a rapid-acting, potent, selective, durable inhibitor of BTK with an initial tolerability profile consistent with the requirements of chronic utilization that is well matched with our targeted indications.

Our Targeted Indications

We selected each of our three initial indications of food allergy, chronic spontaneous urticaria (CSU) and multiple sclerosis (MS) based on the strong mechanistic rationale for VT7208 and the opportunity to balance rapid establishment of human proof of concept with exploration of its broad therapeutic potential. We believe the two allergic indications provide expeditious pathways to clinically meaningful readouts, while MS may offer the opportunity to leverage VT7208's dual peripheral and central activity across multiple forms of a disease with profound unmet need.

Food allergy

Overview

Allergic reactions to certain types of food, including allergies to shellfish and peanuts, occur most commonly when food-allergen-specific IgE, bound to the high-affinity IgE receptor (FcεRI) on the surface of mast cells and basophils misidentifies food proteins as pathogenic causing those cells in turn to release inflammatory mediators upon repeated exposure to the offending food. There is considerable variability in the symptomatic presentation from individuals suffering from an allergic reaction ranging from mild itching and rash to severe, life-threatening anaphylaxis. Approximately 17 million Americans, including an estimated 3.6 million children, suffer from some form of food allergy, and more than 40% of those impacted have experienced at least one reaction categorized as severe in their lifetime.

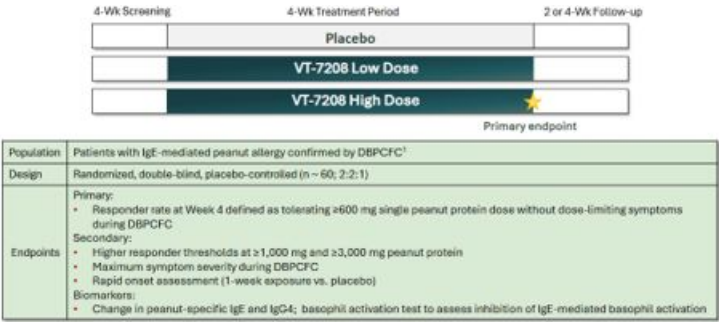
Due to the limited treatment options currently available, food allergies are most often managed through exposure avoidance and rescue therapies as needed.

BTK mechanistic rationale for treating food allergies

As an essential signaling component immediately downstream of FcεRI, BTK is well positioned to disrupt the allergic cascade before mast-cell and basophil activation triggers the allergic reaction that most commonly drives food allergies. We believe this makes BTK inhibition one of the most biologically aligned mechanisms for this indication. Our conviction is further supported by the FDA approval of the injectable treatment Xolair® for food allergies and clinical trial data generated by the oral, twice-daily BTK inhibitor remibrutinib. In a controlled study, one month of BID treatment with remibrutinib led to a clinically relevant, dose-dependent increase in the proportion of patients able to tolerate a peanut-protein oral challenge without dose-limiting symptoms in as little as seven days, with responder rates rising proportionately across ascending doses.

VT7208's potential to differentiate in food allergies

If approved, we believe that VT7208 is well positioned to build on these achievements while also offering potential differentiation as a longer acting, well tolerated, once daily oral treatment which may combine to increase overall treatment adherence and reduce lapses in protection. Given the large pediatric component of the overall food allergy population, this added layer of protection may be particularly compelling to both parents and physicians as it may reduce the risk of accidental exposure by either an unsupervised child or a child in the care of a non-parental third party who is unaware of the allergic risk.



As depicted above, our initial Phase 2 trial in food allergy is planned as a four-week, randomized, controlled study of approximately 60 patients with confirmed IgE-mediated peanut allergy, followed by a two- to four-week follow-up period. Patients will be randomized to low-dose VT7208, high-dose VT7208 or placebo. The primary endpoint will be responder rate, defined as tolerating a single peanut-protein dose of ≥600 mg without dose-limiting symptoms. The secondary endpoints are higher responder thresholds (≥1,000 mg and ≥3,000 mg of peanut protein), maximum symptom severity, and a rapid-onset assessment at one week versus placebo; we will also measure changes in peanut-specific IgE and IgG4 and in basophil activation. We intend to initiate this trial in the second half of 2026 and expect to report proof of concept data in the second half of 2027.

Chronic spontaneous urticaria (CSU)

Overview

CSU is a chronic inflammatory skin disease characterized by the recurrent development of itching, hives (wheals) and angioedema in the absence of a specific external trigger which affects an estimated 1.6 to 2 million U.S. adults with a roughly two-to-one female predominance. Though not typically life-threatening, CSU imposes a significant quality of life burden on patients as they often experience daily or near-daily hives and intense, often nocturnal, itching which leads to sleep disruption, daily productivity losses, and elevated rates of anxiety and depression. It is estimated that at least half of patients remain symptomatic following treatment with second-generation H1-antihistamines, which have long been the standard of care for first line therapy.

BTK mechanistic rationale the for the treatment of CSU

Like food allergies, activation of mast cells and basophils is central to the pathogenesis of CSU, which we believe again positions BTK to arrest the dysregulated immune cascade that drives the disease. This potential was recently validated by the FDA’s September 2025 approval of remibrutinib (Rhapsido®) as the first oral BTK inhibitor for CSU patients who remain symptomatic despite antihistamine therapy, joining omalizumab (Xolair®) and Dupilimab, (Dupixent®) as approved IgE pathway targeting therapies for the condition.

In its pivotal trials, remibrutinib achieved a clinically meaningful improvement of USA7, its primary endpoint, while also driving well-controlled disease in about half of patients and complete responses in roughly a third, with benefits sustained through 52 weeks. One particularly disease relevant differentiating feature of remibrutinib was its speed of onset as patients reported itch improvement within roughly twelve hours of the first dose, in contrast with the more gradual onsets of treatment benefits, often measured in weeks, of omalizumab and dupilimab.

Potential for VT7208 to differentiate from the class in CSU

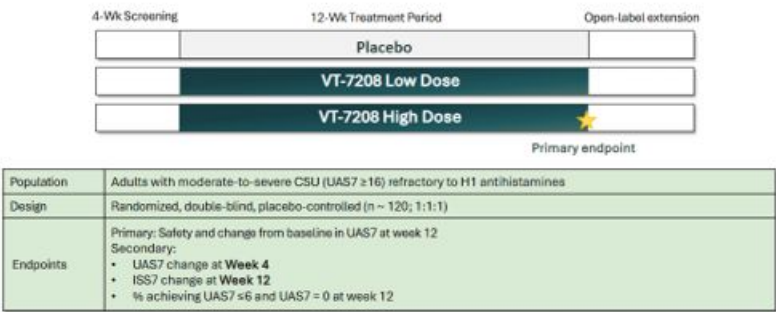
We believe VT7208’s potential for differentiation in CSU rests on three attributes that could be particularly meaningful in the specific context of the patient experience: once daily dosing, speed to onset and durability of symptomatic control.

Once daily dosing. VT7208 is designed for convenient once-daily dosing, and its durable target occupancy has the potential to sustain BTK blockade across the full dose interval versus remibrutinib’s twice-daily regimen which increases the likelihood of an end of treatment interval diminution of effect and missed doses leading to on-treatment symptomatic breakthrough.

Increased speed to onset. VT7208’s rapid pharmacodynamic onset may have the potential to translate into faster symptom relief.

Durability of control. Maintaining long duration relief from the symptoms of CSU without experiencing reemergence could be especially meaningful in this setting given the typical multiyear disease course of CSU marked by continuous, symptomatic burden.

Clinical Development Plans in CSU



As depicted above, our Phase 2 study in CSU is planned as a 12-week study of approximately 120 adults with moderate-to-severe CSU (UAS7 ≥16) who are refractory to H1-antihistamines, with an open-label extension. Patients will be randomized equally to low-dose VT7208, high-dose VT7208 or placebo. The co-primary endpoints will be safety and change from baseline in UAS7 at week 12, with secondary endpoints of UAS7 change at week 4, ISS7 change at week 12, and the proportions of patients achieving UAS7 ≤6 and UAS7 = 0 at week 12. We intend to initiate this trial in the second half of 2026 and expect to report proof of concept data in the first half of 2028.

Multiple Sclerosis (MS)

Overview

MS is a chronic autoimmune disease in which dysregulated immune cells, including B cells, infiltrate the CNS and, together with CNS-resident microglia, drive the inflammation and neurodegeneration that ultimately produce progressive and irreversible disability. Approximately 1.25 million Americans live with MS. The disease is presented in two principal forms:

Relapsing MS

Relapsing MS (RMS), which represents the substantial majority (approximately 1 million) of cases at diagnosis, is defined by discrete attacks of neurological symptoms that typically last for weeks before a remission. These relapses reflect episodes of acute inflammation, producing symptoms such as vision loss, numbness, tingling and fatigue as the immune system attacks the myelin insulating nerve fibers. RMS is the most common presentation at initial diagnosis and the most responsive to currently available disease-modifying therapies.

Progressive MS

Progressive MS (PMS) is defined by a steady, gradual worsening of neurological function and accumulating disability over time, driven less by acute peripheral inflammatory attacks than by ongoing CNS nerve-fiber degeneration, and is considerably less responsive to current treatments. Within progressive MS there are two subtypes: (1) secondary progressive MS (SPMS) develops in approximately 10% of relapsing patients over time, typically years to decades after diagnosis, as accumulated injury shifts the disease from a relapsing-remitting pattern to continuous decline and (2) primary progressive MS (PPMS), which represents an estimated 150,000 annual MS cases, typically presents at an older age and drives disability steadily from onset without a preceding relapsing phase.

Current standard of care

The current first-line MS therapies, anti-CD20 antibodies, which are administered by infusion or injection, deplete circulating B cells in the periphery and have proven highly effective at dramatically reducing the acute attacks that characterize RMS and delaying the onset of SPMS. These therapies, despite being approved in PMS, show more limited benefits once the disease progression is independent of relapse activity. Progression independent of relapse activity (PIRA) and the associated accumulation of disabilities is now understood to be driven by inflammation compartmentalized within the CNS which limits the utility of therapies, like anti-CD20 antibodies, that cannot cross the blood brain barrier. In addition, non-selective B-cell depletion makes no distinction between pathogenic and healthy B cells, which leaves patients at greater risk of infection and frequently unable to mount successful responses to vaccination.

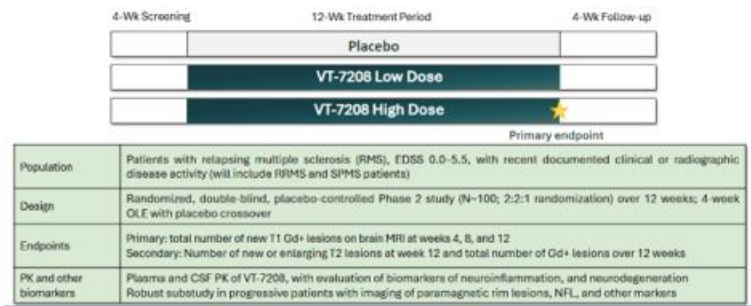
Rationale for a once daily CNS-penetrant BTKi to address the entire MS disease spectrum

We believe that dual inhibition of peripheral and CNS BTK signaling has a compelling rationale for addressing the limitations of the current standard of care B-cell depletion treatments, as it has shown the potential to both modulate pathogenic B cells in the periphery rather than deplete the overall B-cell population and also penetrate the CNS blood-brain barrier to act upon the microglia that drive the smoldering inflammation underlying PIRA/disability progression. This mechanistic benefit of BTK inhibition has been validated by clinical data from tolebrutinib, a once-daily, oral, CNS-penetrant BTK inhibitor which, in clinical trials, demonstrated the ability to both impact relapses and slow disability progression. Tolebrutinib’s development, however, despite receiving an approval from the EMA in PMS, has been hindered in the U.S. by hepatic safety concerns, which we believe underscores VT7208’s potential to fulfill the mechanistic promise of BTK inhibition in MS while addressing the tolerability limitations that have heretofore precluded it from becoming reality.

Potential for VT7208 to differentiate from the class in MS

We believe that once-daily VT7208 holds the potential to improve upon the therapeutic profile demonstrated to date in the class by potentially improving both efficacy and tolerability. VT7208 may have greater impact on CNS-resident inflammation by achieving higher and longer-duration drug concentration levels in the brain, while reducing the likelihood of hepatic impact as a result of its low dose, enhanced target selectivity and stable metabolic profile. If borne out in larger randomized controlled trials, this combination of deeper CNS exposure and improved tolerability would be directly responsive to the two factors that have constrained the CNS-penetrant BTK approach to date in MS.

Clinical Development Plans in MS



As depicted above our Phase 2 RMS study is planned as a 12-week study with a four-week open-label extension in approximately 100 patients with relapsing MS (EDSS 0.0–5.5) who have recent documented clinical or radiographic disease activity, designed to establish early clinical and radiographic evidence of disease impact and to inform potential future registrational RMS and progressive-MS programs. Patients will be randomized to high- or low-dose VT7208 or placebo, with an opportunity for patients initially assigned to placebo to cross over during the open-label extension. The primary endpoint will be the total number of new T1 gadolinium-enhancing lesions on brain MRI at weeks 4, 8 and 12, with secondary endpoints of the number of new or enlarging T2 lesions at week 12 and the total number of gadolinium-enhancing lesions over 12 weeks. We will also assess VT7208's brain penetration by measuring plasma and cerebrospinal-fluid concentrations and its effect on biomarkers of neuroinflammation and neurodegeneration, and we will conduct a sub-study in enrolled progressive patients with imaging of paramagnetic rim lesions, neurofilament light chain (NFL) and other markers. We intend to initiate this trial in the first half of 2027 and expect to report proof of concept data in the second half of 2028.

Commercial Opportunity

We believe there is considerable commercial potential for VT7208, if approved, in each of its targeted indications given the chronic nature of the conditions, the size of the patient populations, the urgency of the unmet medical need and the potential for differentiation. The development of the commercial markets for each of these indication, however, is at varying stages. Both food allergies and CSU are nascent markets for branded therapeutics with many FDA approvals only occurring in within recent years, whereas MS represents a well-established market of more than 25 years with clear predicates for the sales potential of new agents that offer a differentiated profile. Our belief in the commercial potential of VT7208 in food allergy and CSU is therefore based on the large size of the patient populations, approximately 17 million and 1.7 million respectively, and the significant unmet need, while in MS we can base our view on the documented sales totals achieved by MS therapeutics.

In 2025, the total market for branded MS treatments was approximately \$20 billion based on publicly disclosed sales figures with the leading four treatments, Ocrevus® (Roche) Kesimpta® (Novartis), Tysabri® (Biogen) and Mavenclad® (Merck KGaA), each achieving greater than \$1 billion in sales and collectively representing greater than \$15 billion of sales.

We believe our optimism for the commercial potential of the food allergy and CSU markets is supported by the product guidance and public commentary of two leading global pharmaceutical companies who have products that are used to treat both indications: Roche Holding AG and Novartis AG. Roche management specifically credited food allergy as the leading cause of Xolair's® 2025 sales acceleration (+32% growth year-over-year), while Novartis' marketing materials cite remibrutinib, known commercially as Rhapsido® as amongst a group of emerging products with potential to generate at least \$3 billion dollars annually at peak and cited CSU and food allergies as key drivers of that potential. This view has also been expressed in the projection of equities research analysts who forecast Rhapsido to reach \$3 billion in sales by 2029. In addition, development stage biotechnology company, Rapt Therapeutics has stated their lead clinical candidate ozureprubart, a long-acting anti-IgE agent, presents a \$5.5 billion opportunity in food allergy and CSU combined.

Given our stage of development, however, we will not likely achieve any sales for many years, and we have not yet established either a commercial organization or distribution capabilities.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. While we believe the unique attributes of VT7208 provide us with competitive advantages, we face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions and governmental agencies, as well as public and private research institutions. 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. These competitors also compete with us 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 programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The markets for autoimmune and allergic disease therapies are highly competitive and characterized by rapid innovation. In our target indications, we expect to compete with established therapeutic classes as well as other BTK inhibitors that are approved or in clinical development. We believe VT7208’s potential points of differentiation described above may provide meaningful competitive advantages.

Following a comprehensive search of publicly available databases, we have identified the following programs across our targeted indications that may present a competitive threat to our ability to successfully commercialize VT7208, if approved.

Food allergy

Stage	Drug	Sponsor	Mechanism of Action	Route of Administration
Approved	Peanut allergen powder-dnfp (Palforzia)	Stallergenes Greer	Characterized oral immunotherapy (allergen desensitization)	Oral (powder in capsules/sachet, mixed with food)
Approved	Omalizumab (Xolair)	Genentech / Novartis	Anti-IgE monoclonal antibody	Subcutaneous
Phase 3 / BLA filing	Viaskin Peanut patch (DBV712)	DBV Technologies	Epicutaneous immunotherapy (allergen desensitization)	Epicutaneous (skin patch)

Stage	Drug	Sponsor	Mechanism of Action	Route of Administration
Phase 3	Remibrutinib (Rhapsido)	Novartis	Covalent BTK inhibitor	Oral
Phase 3	Epinephrine nasal powder (FMXIN002)	Nasus Pharma	Alpha/beta adrenergic agonist (rescue)	Intranasal (dry powder)
Phase 2	RPT904	RAPT Therapeutics / GSK	Long-acting anti-IgE monoclonal antibody	Injection; Not specified in registry
Phase 2	LP-003	Longbio Pharma	Anti-IgE monoclonal antibody	Injection; Not specified in registry
Phase 2	Tezepelumab	NIAID (CoFAR)	Anti-TSLP monoclonal antibody	Subcutaneous
Phase 2	Dupilumab (Dupixent)	Regeneron / Sanofi	Anti-IL-4R α monoclonal antibody (blocks IL-4/IL-13)	Subcutaneous
Phase 2	Acalabrutinib	Johns Hopkins University	BTK inhibitor	Oral
Phase 2	Abatacept	Investigator-led (CHU Sainte-Justine)	CTLA4-Ig T-cell costimulation blocker (adjuvant to oral immunotherapy)	Subcutaneous or intravenous; Not specified in registry
Phase 2	PVX-108	Aravax	T-cell peptide immunotherapy	Injection; Not specified in registry
Phase 2	ADP101	Alladapt Immunotherapeutics	Multi-food characterized oral immunotherapy	Oral
Phase 2	Peanut SLIT-tablet	ALK-Abelló	Sublingual allergen immunotherapy	Sublingual (tablet)
Phase 2	INP20	InnoUp Farma	Nanoparticle-encapsulated oral immunotherapy	Oral
Phase 2	VE416 ($\pm$ vancomycin)	Massachusetts General Hospital / Vedanta	Live bacterial consortium (microbiome modulation) with peanut OIT	Oral (capsule)
Phase 2	ENP-501	N-Fold	Allergen immunotherapy	Not specified in registry
Phase 2	UKK-0018	Ukko	Undisclosed (immune re-education)	Injection; Not specified in registry
Phase 1	IGNX001	IgGenix	Human anti-peanut IgG allergen-blocking antibody	Injection; Not specified in registry
Phase 1	MY006	Mabylon	Allergen-blocking human antibody	Subcutaneous
Phase 1	LCA-0061	Lycia Therapeutics	Extracellular IgE-degrading bifunctional molecule	Subcutaneous
Phase 1	Linvoseltamab + dupilumab	Regeneron	BCMA $\times$ CD3 bispecific (plasma-cell depletion) + anti-IL-4R α	Intravenous (linvoseltamab) + subcutaneous (dupilumab)
Phase 1	Abrocitinib	Icahn School of Medicine at Mount Sinai	JAK1 inhibitor	Oral
Phase 1	INT301	Intromune Therapeutics	Oral-mucosal allergen immunotherapy (toothpaste)	Oral mucosal (toothpaste)
Phase 1	VLP Peanut	Allergy Therapeutics / Saiba	Virus-like-particle peanut allergen vaccine	Not specified in registry
Phase 1	HAL-MPE1	HAL Allergy	Chemically modified, alum-adsorbed peanut allergen extract	Subcutaneous
Phase 1	IN-001 epinephrine sublingual spray	Insignis Therapeutics	Alpha/beta adrenergic agonist (rescue)	Sublingual (spray)

Stage	Drug	Sponsor	Mechanism of Action	Route of Administration
Approved	Cetirizine, levocetirizine, fexofenadine, bilastine, desloratadine, rupatadine (2nd-gen H1 antihistamines)	Multiple	Histamine H1-receptor inverse agonist (first-line, up to 4x dose in guidelines)	Oral
Approved	Omalizumab (Xolair)	Genentech / Novartis	Anti-IgE monoclonal antibody	Subcutaneous
Approved	Remibrutinib (Rhapsido)	Novartis	Covalent BTK inhibitor	Oral (tablet)
Approved	Dupilumab (Dupixent)	Regeneron / Sanofi	Anti-IL-4R α monoclonal antibody (blocks IL-4/IL-13)	Subcutaneous
Phase 3 / BLA filing	Barzolvolimab (CDX-0159)	Celldex Therapeutics	Anti-KIT monoclonal antibody (mast-cell depletion)	Subcutaneous
Phase 3	JYB1904	Jemincare	Anti-IgE monoclonal antibody	Subcutaneous injection
Phase 3	CMAB007	Taizhou Mabtech	Omalizumab biosimilar (anti-IgE mAb)	Subcutaneous
Phase 2/3	ICP-332	InnoCare Pharma	TYK2 (JH2) inhibitor	Oral (tablet)
Phase 2	Briquilimab	Jasper Therapeutics	Anti-KIT monoclonal antibody (mast-cell depletion)	Subcutaneous
Phase 2	Rilzabrutinib	Sanofi	Reversible covalent BTK inhibitor	Oral
Phase 2	Povorcitinib	Incyte	JAK1 inhibitor	Oral
Phase 2	TAS5315	Taiho Pharmaceutical	BTK inhibitor	Oral
Phase 2	Fenebrutinib (GDC-0853)	Genentech	Non-covalent BTK inhibitor	Oral
Phase 2	EVO756	Evommune	Oral MRGPRX2 antagonist (mast-cell activation blocker)	Oral
Phase 2	EP262	Escient Pharmaceuticals	MRGPRX2 antagonist	Oral
Phase 2	UB-221	United BioPharma	Anti-IgE monoclonal antibody (binds IgE and CD23)	Intravenous infusion
Phase 2	YH35324	Yuhan Corporation	High-affinity IgE Trap-Fc fusion protein	Subcutaneous
Phase 2	Tezepelumab	Amgen / AstraZeneca	Anti-TSLP monoclonal antibody	Subcutaneous
Phase 2	TLL-018	Highlightl Pharmaceutical	JAK1/TYK2 inhibitor	Oral (tablet)
Phase 2	CM512	Keymed Biosciences	Not specified in registry	Injection; Not specified in registry
Phase 2	LP-003	Longbio Pharma	Anti-IgE monoclonal antibody	Injection; Not specified in registry
Phase 2	BBT001	Bambusa Therapeutics	Not specified in registry	Injection; Not specified in registry
Phase 2	Ritlecitinib	Investigator-led (Mount Sinai)	JAK3 / TEC-family kinase inhibitor	Oral
Phase 1	AK006	Allakos	Anti-Siglec-6 monoclonal antibody (mast-cell inhibition)	Intravenous and subcutaneous
Phase 1	HRS-3095	Hengrui / Atridia	Not specified in registry	Not specified in registry

Stage	Drug	Sponsor	Mechanism of Action	Route of Administration	Patient Population
Approved	Interferon beta-1a (Avonex, Rebif)	Biogen; EMD Serono	Type I interferon immunomodulator	Intramuscular (Avonex) / subcutaneous (Rebif)	Relapsing forms of MS (CIS, RRMS, active SPMS), adults
Approved	Peginterferon beta-1a (Plegridy)	Biogen	PEGylated type I interferon	Subcutaneous or intramuscular	Relapsing forms of MS (CIS, RRMS, active SPMS), adults
Approved	Interferon beta-1b (Betaseron, Extavia)	Bayer; Novartis	Type I interferon immunomodulator	Subcutaneous	Relapsing forms of MS (CIS, RRMS, active SPMS), adults
Approved	Glatiramer acetate (Copaxone, Glatopa)	Teva; Sandoz	Random amino-acid copolymer; immune deviation	Subcutaneous	Relapsing forms of MS (CIS, RRMS, active SPMS), adults
Approved	Teriflunomide (Aubagio + generics)	Sanofi; generics	Dihydroorotate dehydrogenase (pyrimidine synthesis) inhibitor	Oral (tablet)	Relapsing forms of MS (CIS, RRMS, active SPMS), adults
Approved	Dimethyl fumarate (Tecfidera + generics)	Biogen; generics	Nrf2 activator / immunomodulator	Oral (DR capsule)	Relapsing forms of MS (CIS, RRMS, active SPMS), adults
Approved	Diroximel fumarate (Vumerity)	Biogen	Nrf2 activator (MMF prodrug)	Oral (DR capsule)	Relapsing forms of MS (CIS, RRMS, active SPMS), adults
Approved	Monomethyl fumarate (Bafiertam)	Banner Life Sciences	Nrf2 activator (active fumarate metabolite)	Oral (DR capsule)	Relapsing forms of MS (CIS, RRMS, active SPMS), adults
Approved	Fingolimod (Gilenya + generics)	Novartis; generics	S1P receptor modulator (non-selective)	Oral (capsule)	Relapsing forms of MS (CIS, RRMS, active SPMS), patients ≥ 10 years
Approved	Siponimod (Mayzent)	Novartis	S1P1/S1P5 receptor modulator	Oral (tablet)	Relapsing forms of MS (CIS, RRMS, active SPMS), adults — positioned for active SPMS
Approved	Ozanimod (Zeposia)	Bristol Myers Squibb	S1P1/S1P5 receptor modulator	Oral (capsule)	Relapsing forms of MS (CIS, RRMS, active SPMS), adults
Approved	Ponesimod (Ponvory)	Johnson & Johnson	S1P1 receptor modulator	Oral (tablet)	Relapsing forms of MS (CIS, RRMS, active SPMS), adults
Approved	Cladribine (Mavenclad + generics)	EMD Serono; generics	Purine analogue; selective lymphocyte depletion	Oral (tablet)	RRMS and active SPMS, adults (not for CIS); after inadequate response to another DMT

Stage	Drug	Sponsor	Mechanism of Action	Route of Administration	Patient Population
Approved	Natalizumab (Tysabri; biosimilar Tyruko)	Biogen; Sandoz	Anti- α 4-integrin mAb (blocks CNS lymphocyte trafficking)	Intravenous (also SC in EU)	Relapsing forms of MS (CIS, RRMS, active SPMS), adults
Approved	Ocrelizumab (Ocrevus; Ocrevus Zunovo SC)	Genentech / Roche	Anti-CD20 B-cell-depleting mAb	Intravenous; subcutaneous with hyaluronidase	Relapsing forms of MS (CIS, RRMS, active SPMS) in adults; PPMS in adults; RRMS in children ≥ 10 years
Approved	Ofatumumab (Kesimpta)	Novartis	Anti-CD20 B-cell-depleting mAb	Subcutaneous (autoinjector)	Relapsing forms of MS (CIS, RRMS, active SPMS), adults
Approved	Ublituximab (Briumvi)	TG Therapeutics	Glycoengineered anti-CD20 mAb	Intravenous	Relapsing forms of MS (CIS, RRMS, active SPMS), adults
Approved	Alemtuzumab (Lemtrada)	Sanofi	Anti-CD52 depleting mAb (immune reconstitution)	Intravenous	Relapsing forms of MS (CIS, RRMS, active SPMS), adults; reserved for inadequate response to ≥ 2 DMTs
Approved	Mitoxantrone (Novantrone + generics)	Generics	Type II topoisomerase inhibitor / immunosuppressant	Intravenous	SPMS, progressive-relapsing MS, or worsening RRMS
Approved (symptomatic)	Dalfampridine (Ampyra + generics)	Amneal; generics	Potassium-channel blocker (improves walking speed)	Oral (ER tablet)	Any MS subtype, adults — symptomatic, not disease-modifying
Approved (EU) / FDA CRL	Tolebrutinib (Cenrifki)	Sanofi	CNS-penetrant covalent BTK inhibitor	Oral	nrSPMS — EU approval June 2026 (HERCULES, NCT04411641; 31% reduction in 6-month CDP). FDA CRL Dec 2025 citing severe DILI risk and no subgroup with favorable benefit-risk. Provisionally approved UAE Jul 2025. PPMS (PERSEUS, NCT04458051) missed its primary endpoint; RMS GEMINI 1/2 missed primary but met pooled disability worsening.
Phase 3	Fenebrutinib	Genentech / Roche	CNS-penetrant non-covalent BTK inhibitor	Oral	RMS (FENhance 1/2) and PPMS (FENtrepid)
Phase 3	Frexalimab (SAR441344)	Sanofi	Anti-CD40L mAb (costimulation blockade)	Intravenous and subcutaneous	RMS (FREXALT) and nrSPMS (FREVIVA)
Phase 3	Vidofludimus calcium (IMU-838)	Immunix	DHODH inhibitor / Nurr1 activator	Oral (tablet)	RRMS (ENSURE 1/2) and PMS (CALLIPER)
Phase 3	Divozilimab (BCD-132)	Biocad	Anti-CD20 mAb	Intravenous	RRMS / SPMS (Russia)
Phase 3	Remibrutinib	Novartis	Covalent BTK inhibitor	Oral	RMS (NCT05147220, NCT06846281) and SPMS (NCT07225504)

Stage	Drug	Sponsor	Mechanism of Action	Route of Administration	Patient Population
Phase 3	Orelabrutinib	InnoCare / Biogen	Covalent BTK inhibitor	Oral	RRMS (Phase 2); Phase 3 in SPMS (NCT07299019) and PPMS (NCT07067463)
Phase 3	Simvastatin	UCL (MS-STAT2)	HMG-CoA reductase inhibitor; neuroprotection	Oral	SPMS (MS-STAT2, NCT03387670)
Phase 3 (suspended)	Masitinib	AB Science	Tyrosine kinase inhibitor (mast cell / microglia)	Oral	Non-active SPMS and PPMS (NCT05441488 suspended)
Phase 2/3	CNM-Au8	Clene Nanomedicine	Catalytic gold nanocrystal (CNS bioenergetics / remyelination)	Oral (suspension)	RMS with chronic optic neuropathy (NCT04626921)
Phase 2	BIIB091	Biogen	BTK inhibitor ($\pm$ diroximel fumarate)	Oral	Relapsing forms of MS
Phase 2	KYV-101	Kyverna Therapeutics / academic sites	Fully human autologous CD19 CAR-T	Intravenous (single infusion)	Progressive MS (PPMS and SPMS)
Phase 2	Obexelimab	Zenas BioPharma	Bifunctional CD19 $\times$ Fc γ RIIb inhibitory antibody	Subcutaneous	Relapsing MS
Phase 2	Foralumab	Tiziana Life Sciences	Nasal anti-CD3 mAb (regulatory T-cell induction)	Intranasal	Non-active SPMS
Phase 2	Autologous HSCT	Academic consortia (e.g. BEAT-MS)	Immunoablation and immune reconstitution	Intravenous (transplant procedure)	Relapsing MS refractory to DMTs; also progressive MS
Phase 2	Clemastine fumarate	UCSF (investigator-led)	H1 antihistamine repurposed as remyelinating agent (M1R antagonism)	Oral	RRMS with chronic optic neuropathy
Phase 2	Metformin ($\pm$ clemastine)	Academic (Cambridge/UCL)	AMPK activator; OPC rejuvenation / remyelination	Oral	RRMS and progressive MS
Phase 1/2	Rapcabtagene autoleucel (YTB323)	Novartis	Autologous CD19 CAR-T (B-cell reset)	Intravenous (single infusion)	RMS (NCT06617793) and progressive MS (NCT06675864)
Phase 1/2	PIPE-307	Contineum Therapeutics / J&J	Selective M1 muscarinic receptor antagonist (remyelination)	Oral	RRMS

Intellectual Property

A key component of our business is generating, protecting, and enhancing proprietary technology, inventions, improvements and other rights that are commercially important to our business, including seeking, maintaining and defending patent rights, trademark rights, and trade secrets. With respect to patents, our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. We additionally rely on data exclusivity and market exclusivity. Our commercial success will depend in part on our ability to obtain and maintain patents and other proprietary protection for our technology, inventions, and improvements; to preserve the confidentiality of our trade secrets; to maintain our licenses to use intellectual property owned by third parties; to defend and enforce our proprietary rights, including our patents; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

Our intellectual property strategy is intended to protect the VT7208 composition of matter, and its methods of use across our target indications. As of August 31, 2026, we currently hold an issued patent in the United States and pending patent applications in various jurisdictions, including Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, Japan, Korea, New Zealand, Singapore, and the United States, covering the composition of matter, and uses of VT7208.

Agreement with Gossamer

On May 17, 2024, we entered into an Agreement and Plan of Merger (the Gossamer Agreement) with Gossamer Bio, Inc. (Gossamer) and GB005, Inc. (GB005), a wholly-owned subsidiary of Gossamer, and our wholly-owned subsidiary, Vidya Merger Sub, Inc. Pursuant to the Gossamer Agreement, Vidya Merger Sub, Inc. merged with and into GB005, with GB005 surviving as our wholly-owned subsidiary. Through this acquisition, we obtained Gossamer's BTK inhibitor program, including certain compounds (the Gossamer Compounds) and related program assets. In consideration of the transaction, we made an initial cash payment to Gossamer of \$250,000. The Gossamer Agreement additionally provided for future contingent cash payments consisting of:

- one-time development and regulatory milestone payments upon achievement of specified milestone events, up to an aggregate of \$165.5 million, with each milestone payment payable only once upon first achievement of the applicable milestone;
 - tiered net sales-based earn-out payments on sales of products derived from the Gossamer Compounds at rates ranging from low- to mid-single digit percentages depending on certain annual net sales thresholds, payable on a product-by-product and country-by-country basis during the applicable term, which begins on the first commercial sale of such product in a country and continues until the latest of (i) expiration of the last valid patent claim covering such product in that country, (ii) expiration of any period of regulatory exclusivity in that country, and (iii) the fifteenth anniversary of first commercial sale of such product in that country, subject to a 50% reduction on a product-by-country basis where there is neither patent coverage nor regulatory exclusivity or where there is an approved generic entrant; and
 - if we undergo a qualifying transaction involving a change of control of the Company, sale of the Gossamer Compounds or substantially all of the program assets, subject to certain exceptions, Gossamer has the option, exercisable within 5 days of notice of the transaction, to elect to receive a payment from us equal to 2.5% of the consideration in such qualifying transaction up to \$200 million and 5.0% of the consideration in such qualifying transaction above \$200 million, in lieu of any further milestone, sales-based, or other contingent payments; upon such election, all such further payments terminate. For the avoidance of doubt, no payments were made to Gossamer in connections with the Vidya acquisition.
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All milestone, sales-based, and acquisition-based payments are subject to a 20% reduction (applied on a country-by-country basis where the partnership does not cover the United States or the European Union and United Kingdom in their entirety) if we enter into an exclusive or co-exclusive third-party license covering the development, marketing, or commercialization of any Gossamer Compound or the assets that includes the United States, or the European Union (in its entirety) and the United Kingdom. Sales-based payments may additionally be reduced by up to 50% (in any year) to reflect royalties we pay to a third party for intellectual property rights necessary to manufacture or sell a product.

Our liability for indemnification claims under the Gossamer Agreement is limited solely to a right of setoff, on a dollar-for-dollar basis, against any contingent payments otherwise payable to Gossamer, subject to a certain deductible (which does not apply to tax-related claims). Other than for tax-related claims, our maximum recovery is further capped at 50% of each of the first three development milestone payments and 5% of each of the remaining development milestone payments, which in the aggregate equals \$15.25 million. The Gossamer Agreement contained representations and warranties customary for a transaction of this type.

Legacy Processa Intellectual Property

Our current patent portfolio with respect to the legacy Processa assets consists of the number of patents related to our drug candidates licensed from each third-party licensor. In addition to the international patents and/or international and U.S. patent applications licensed from our third-party licensors, we have licensed at least the following number of U.S. patents:

	Sun Pharmaceuticals	Yuhan	Aposense	Total
U.S. patents	9	6	3	17

Besides relying on patents, we may also rely on trade secrets, proprietary know-how and continuing innovation to develop and maintain our competitive position with respect to the legacy Processa assets, especially when we do not believe that patent protection is appropriate or can be obtained. In addition, we continuously evaluate opportunities to obtain exclusivity through our regulatory filings with the FDA. We seek protection of these trade secrets, proprietary know-how and any continuing innovation, in part, through confidentiality and proprietary information agreements. However, these agreements may not provide meaningful protection for, or adequate remedies to protect, our technology in the event of unauthorized use or disclosure of information. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors.

Chemistry, Manufacturing, and Controls

We do not currently own or operate, and have no plans to establish, any manufacturing facilities. All of our preclinical and clinical drug supply development, manufacturing, storage, distribution, and testing is outsourced to third-party manufacturers and facilities. Our manufacturing strategy enables us to more efficiently direct financial resources to the research, development, and commercialization of VT7208 rather than diverting resources to internally develop and maintain manufacturing facilities.

The quality and amount of the current VT7208 drug supply (DS) and drug product (DP) is appropriate for our current and expected Phase 2 trials. Further CMC development is ongoing, including activities leading to the manufacture of batches in support of potential future registrational trials, NDA submissions, and required regulatory validation of DS/DP manufacturing processes in anticipation of any potential commercial launch.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, pricing, reimbursement, marketing, import and export of pharmaceutical products such as those Slate is developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations require the expenditure of substantial time and financial resources. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of certain preclinical laboratory tests, animal studies and formulation studies in accordance with Good Laboratory Practice regulations (GLPs) and other applicable regulations;
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- submission to the FDA of an Investigational New Drug application (IND), which must become effective before human clinical trials may begin;
- approval by an independent institutional review board (IRB), or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice regulations (GCPs) to evaluate the safety and efficacy of the product candidate for its intended use;
- preparation and submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice requirements (cGMPs) to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND. An IND is a request for allowance from the FDA to administer an investigational drug product to humans. An IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and any effectiveness criteria to be evaluated. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about on-going or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs, which include, among other things, the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB covering the institutions participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries, including clinicaltrials.gov.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects, or in some cases, patients with the target disease or condition, and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.
 - Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance and appropriate dosage.
 - Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.
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Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial regulatory approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMPs. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Process

The results of product development, including results from preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, the Pediatric Research Equity Act (PREA), requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, NDAs and certain supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Once an NDA has been submitted, the FDA conducts a preliminary review of the application within the first 60 days after submission, before accepting it for filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act (PDUFA), guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted. The FDA's review of the application may also be extended for a three-month period to enable the FDA to respond to new information deemed a "major amendment" to the application.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCPs. After the FDA evaluates an NDA and conducts any required inspections of clinical trial sites or the manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter (CRL). An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the NDA addressing all of the deficiencies identified in the letter, or otherwise withdraw the application. Even if responsive data and information are submitted, the FDA may decide that the resubmitted NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approved indications for use may more be limited than those initially sought by the Sponsor, which may restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct post-marketing studies to further evaluate the safety or efficacy of the product, and may require additional testing and surveillance programs to monitor the safety of the commercialized product. The FDA may also place other conditions on approval, including the requirement for a Risk Evaluation and Mitigation Strategy (REMS), to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS, which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA will not approve an NDA without an approved REMS, if required. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of drug products.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational drug. For example, the fast track designation program is intended to expedite or facilitate the process for developing and reviewing product candidates that meet certain criteria. Specifically, investigational drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. With regard to a fast track product candidate, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development if preliminary clinical evidence indicates that the product candidate, whether alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior FDA managers.

In addition, an NDA may also be eligible for priority review if the underlying product candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of a NDA designated for priority review in an effort to facilitate the review. The FDA endeavors to review priority review applications within six months of the filing date as compared to ten months for review of new molecular entity NDAs under current PDUFA review goals.

In addition, depending on the design of the applicable clinical trials, a product candidate may be eligible for accelerated approval. Specifically, drugs intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials, and may require that such confirmatory trials be underway prior to granting accelerated approval. Drugs receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory trials in a timely manner or if such trials fail to verify the predicted clinical benefit. In addition, the FDA requires as a condition of accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-approval requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws and regulations. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of requirements for post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on ongoing or planned clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

In addition, the FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Marketing exclusivity

Regulatory exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications that seek to reference an FDA-approved product. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an Abbreviated New Drug Application (ANDA), or an NDA submitted under section 505(b)(2) of the FDCA (505(b)(2) NDA) for another version of such drug where the applicant does not own or have a legal right of reference to such data, if required for approval. However, such applications may be submitted after four years if it contains “Paragraph IV” certification attesting that the new product will not infringe the already approved product’s listed patents, or that such patents are invalid.

The FDCA alternatively provides three years of non-patent exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs referencing the approved application for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA that does not reference the approved application. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. If granted, pediatric exclusivity provides for the attachment of an additional six months of marketing exclusivity to the term of any existing regulatory exclusivity or certain listed patents. Pediatric exclusivity is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve certain applications. A product candidate may be eligible for this six-month period of exclusivity if the NDA sponsor conducts clinical trials in children and submits information requested in writing by the FDA, referred to as a Written Request, relating to the use of the product’s active moiety in children. The issuance of a Written Request does not require the sponsor to undertake the described clinical trials. In addition, the clinical trial data do not need to show the product to be effective in the pediatric population studied; rather, the additional protection is granted if the pediatric clinical trial is deemed to have fairly responded to the FDA’s Written Request. Although the FDA may issue a Written Request for studies on either approved or unapproved indications, it may only do so where it determines that information relating to that use of a product candidate in a pediatric population, or part of the pediatric population, may produce health benefits in that population.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business, which may constrain the financial arrangements and relationships through which we conduct research, as well as sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, and physician and other health care provider transparency laws and regulations. Violation of any of these laws or any other governmental regulations that apply include, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, additional reporting requirements and/or oversight if the manufacturer becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion from participation in federal and state healthcare programs and imprisonment.

Coverage and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing reimbursements for medical products, drugs, and services. In addition, the U.S. government, state legislatures, and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand and also have a material adverse effect on sales.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively the ACA) was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain “branded prescription drugs” to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory cap on drug manufacturers' Medicaid drug rebate program liability, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which went into effect in January 2026, and the subsequent 15 drugs, which will first be effective in 2027, as well as the next set of 15 drugs that will be subject to price negotiations. HHS has issued and will continue to issue guidance implementing the IRA, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The Trump administration is also pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for any product candidate that we commercialize. On the one hand, President Trump threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers entered into confidential pricing agreements with the federal government. In April 2026, the Trump administration issued a proclamation imposing tariffs under Section 232 of the Trade Expansion Act on imports of brand pharmaceuticals, biologics and associated pharmaceutical ingredients, beginning July 31, 2026. Exempted from these tariffs, among others, are companies that have executed or are negotiating agreements with the federal government regarding most favored nation pricing and onshoring of production and research and development. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. While the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. Some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries. These types of initiatives may result in additional reductions in Medicare, Medicaid, and other healthcare funding, and may otherwise affect the prices we may obtain for our investigational products that receive approval. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. Adoption of other new legislation or regulation at the federal, state, or foreign level could further limit reimbursement for pharmaceuticals, including our product candidates if approved.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates, if approved, or additional pricing pressures.

Data Privacy and Security Laws

Numerous state, federal, and foreign laws, regulations and standards govern the collection, use, access to, confidentiality, and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. In particular, the General Data Protection Regulation 2016/679 (GDPR) and implementing legislation in individual European countries impose specific compliance obligations relating to the processing and transfer of personal data of natural persons, including certain kinds of clinical trial data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Operating Digital Asset Treasury Strategy

On August 7, 2025, we announced that we were evaluating corporate digital asset treasury strategies as part of our broader financial and growth objectives and commenced certain strategic engagement with emerging financial technologies, including select digital assets such as CHZ and other cryptocurrencies, tokens, and rights of a similar nature (collectively, Digital Assets) that we believed possessed potential yield-generating capabilities. As of June 30, 2026, we had 26.517 million CHZ tokens, with a cost basis of approximately \$1.0 million and fair value of \$472,003. We are currently evaluating our Digital Asset strategy.

Corporate Information

We were incorporated under the laws of the State of Delaware in 2011. Our principal executive offices are located at 601 21st Street, Suite 300 Vero Beach, FL 32960 and our telephone number is (772) 453-2899.

Facilities

We are currently a remote-based company with a distributed workforce, and substantially all of our employees work remotely. We do not own any real property and to the extent we need additional or alternative space, we believe we can find suitable space in the future on commercially reasonable terms.

Legal Proceedings

From time to time, we have been involved in and may be involved in legal proceedings arising in the ordinary course of our business.

On July 23, 2026, we entered into a settlement agreement with Elion Oncology, Inc. (Elion) to resolve all claims arising from the parties' litigation concerning the license agreement dated August 23, 2020, relating to the commercialization of PCS6422 that was previously being developed in advanced/metastatic breast cancer (the Elion License Agreement). Under the settlement agreement, the Elion License Agreement was terminated, the PCS6422 program was returned to Elion, and the parties exchanged mutual releases of all claims relating to the Elion License Agreement, the PCS6422 program, and the related litigation. In connection with the settlement, we paid Elion \$650,000 towards its attorneys' fees and other out-of-pocket costs. we agreed to grant to Elion a non-voting equity interest equal to 7.5% of the fully diluted pre-money equity capitalization of any newly formed entity (NewCo) whose assets include one or more of PCS499, PCS11-T and/or PCS12852, if the formation or spin-out of NewCo is completed within 365 days following the effective date of the settlement agreement. On August 7, 2026, the stipulation of dismissal became effective, resulting in the dismissal of the litigation with prejudice.

On December 3, 2024, Jason Assad and Marc Gyimesi, two of the investors in our February 2021 private offering, filed a lawsuit that has been assigned to the Commercial Division of the Supreme Court of the State of New York, New York County alleging fraud and negligent misrepresentation in connection therewith regarding alleged company communication and statements and are seeking monetary damages. In addition to being an investor, Mr. Assad was a former investor relations and communications consultant to the Company from September 1, 2021 through June 30, 2024. On April 25, 2025, the Company filed a motion to dismiss the complaint in its entirety. The motion was decided in September 2025. The court dismissed two of the three counts of the complaint (for constructive fraud and negligent misrepresentation) and dismissed that part of the remaining cause of action for fraud to the extent that it related to the retention of Plaintiffs' investment (leaving only the portion of the claim in which Plaintiffs allege they were fraudulently induced to invest in the Company in February 2021). The court also dismissed all claims against Patrick Lin and George Ng. Our and David Young's answer was submitted during October 2025. In January 2026, Plaintiffs were granted leave to amend their complaint to add a claim for breach of contract against us and David Young based on the same factual allegations. Our and David Young's response to the amended complaint (a motion to dismiss) was submitted on March 2, 2026 and is still pending before the Court. At the Court's request, we also filed a non-substantive submission concerning oral argument. We expect to draft and file a motion for summary judgment in the fourth quarter.

We intend to vigorously defend ourselves in these lawsuits and cannot at this time predict the likely outcome of any litigation, reasonably determine either the probability of a material adverse result or any estimated range of potential exposure, or reasonably determine how these matters or any future matters might impact our business, our financial condition, or our results of operations, although such impact, including the costs of defense, as well as any judgments or indemnification obligations, among other things, could be materially adverse to us.

Employees and Human Capital Resources

As of September 15, 2026, we had 9 full-time employees, 3 of whom are primarily engaged in research, development and manufacturing activities, and 1 of whom have an M.D. and/or Ph.D. Our employees are important to the achievement of the company’s mission and goals.

RISK FACTORS

You should carefully consider the risks described below, as well as general economic and business risks and the other information herein. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

SUMMARY OF RISK FACTORS

The risk factors summarized below could materially harm our business, operating results, and/or financial condition, impair our future prospects, and/or cause the price of our common stock to decline. These risks are discussed more fully below. Material risks that may affect our business, financial condition, results of operations, and trading price of our common stock include the following:

- We have a limited operating history and have had a history of significant losses since our inception. We may incur losses over the next several years and may never achieve or maintain profitability.
- We will need substantial additional funding to complete the development of our product candidates. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts. Our development efforts are in the early stages. If we are unable to advance VT7208 or any other product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Our business is highly dependent on the success of VT7208. VT7208 will require additional clinical and manufacturing development before we may be able to seek regulatory approval for and launch a product commercially and we may not be successful in our efforts.
- If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patients are enrolled and additional data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We will depend on timely enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Clinical trials are difficult to design and implement, can be lengthy and expensive, involve uncertain outcomes and may not ultimately be successful.
- We currently rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such clinical trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates.
- If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if approved.

- We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- If we are unable to obtain and maintain effective patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or prevent our development and commercialization efforts.
- There is no guarantee that the Merger will increase stockholder value.
- Pursuant to the terms of the Merger, we are required to recommend that our stockholders approve the conversion of all outstanding shares of our Series A Preferred Stock into shares of our common stock. We cannot guarantee that our stockholders will approve these matters, and if they fail to do so we may be required to settle such shares in cash and our operations may be materially harmed.
- We and the third parties with whom we work are subject to rapidly changing and increasingly stringent U.S. and foreign laws, regulations, and rules; contractual obligations; industry standards; policies and other obligations relating to privacy, data protection and information security. Our actual or perceived failure (or that of the third parties with whom we work) to comply with these obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of business operations (including clinical trials); reputational harm; loss of revenue or profits; and other adverse business consequences. The failure to successfully integrate the businesses of the Company and Vidya in the expected timeframe could adversely affect our results of operations, financial condition, and future results.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and have a history of significant losses since our inception. We may incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess the future viability of our business prospects. Our operations to date have been limited to business planning, including the Merger, organizing and staffing our company, raising capital, identifying potential product candidates, conducting clinical trials and preclinical studies for our development programs, entering into licensing agreements, establishing and enhancing our intellectual property portfolio, and providing general and administrative support for these operations.

We have a history of significant net losses since our inception. Our net loss was \$6.6 million and \$6.8 million for the six months ended June 30, 2026 and 2025, respectively, and \$13.6 million and \$11.9 million for the years ended December 31, 2025 and 2024, respectively. As of June 30, 2026 and as of December 31, 2025, we had an accumulated deficit of \$107.4 million and \$100.8 million, respectively. We have funded our operations to date primarily with proceeds from the sale of our equity securities.

We have no products approved for commercial sale, have not generated any revenue from commercial sales of our product candidates, and are devoting substantially all of our financial resources and efforts to the research and development of VT7208. Investment in clinical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and/or become commercially viable.

We expect that it will take at least several years until any of our product candidates receive marketing approval and are commercialized, and we may never be successful in obtaining marketing approval and commercializing product candidates. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. These net losses will adversely impact our stockholders' equity and net assets and may fluctuate significantly from quarter to quarter and year to year.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. Achievement will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining regulatory approval, manufacturing, marketing and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with the development and commercialization of therapeutic product candidates, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve and maintain profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase and profitability could be further delayed.

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 common stock and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations. A decline in the value of our common stock could also cause you to lose all or part of your investment.

Our operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

As an organization, we have not demonstrated an ability to successfully complete clinical trials, obtain regulatory approvals, manufacture our product candidates at commercial scale or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful commercialization, or obtain reimbursement in the countries of sale. We may encounter unforeseen expenses, difficulties, complications, and delays in achieving our business objectives. Our operating history makes any assessment of our future success or viability subject to significant uncertainty, particularly with respect to the Merger. If we do not address these risks successfully or are unable to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities, then our business will suffer.

We will need substantial additional funding to complete the development of our product candidates. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Since our inception, we have used substantial amounts of capital to fund the development of our product candidates and operations. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as our product candidates enter and advance through preclinical studies and clinical trials. We will require substantial additional funding to meet our financial needs and to pursue our business objectives. We will require significant additional capital to, among other things:

- complete our ongoing and planned clinical trials, preclinical studies and Investigational New Drug Application (IND)-enabling activities;
- initiate, enroll, and complete additional clinical trials for our product candidates;

- seek and obtain regulatory approvals for our product candidates;
- build and maintain our manufacturing capabilities or enter into third-party manufacturing arrangements;
- expand and protect our intellectual property portfolio; and
- fund our general and administrative operations.

In addition, if we obtain marketing approval for any of our product candidates, we will incur significant commercialization expenses related to marketing, sales, administration and manufacturing and distribution.

Failure to raise capital as and when needed would have a negative impact on our financial condition and ability to develop our product candidates. Furthermore, we cannot be certain that additional funding will be available on acceptable terms. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives, and any of our current or future license agreements may be terminated if we are unable to meet the payment or other obligations under the agreements.

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

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, research and development activities and costs associated with operating a public company. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through any or a combination of securities offerings, debt financings, license and collaboration agreements and research grants. If we raise capital through securities offerings, such sales are likely to result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

To the extent that we raise additional capital through the sale of equity, warrants to purchase equity, and/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 stockholder. Debt financing and preferred equity financing, if available, could result in fixed payment obligations, and we may be required to accept terms that restrict our ability to incur additional indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions.

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, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to a third party to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our stockholders, and may cause the market price of our common stock to decline.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish some rights to our technologies or our product candidates on terms that are not favorable to us. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved. If we are unable to raise capital when needed or on attractive terms, we could be forced to further delay, reduce or altogether cease our research and development programs or future commercialization efforts.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such as pandemics, political crises, geopolitical events, or other macroeconomic conditions, which have in the past and may in the future negatively impact our business and financial performance.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability, due to reasons including, among other things, geopolitical conflicts, political changes and trends such as protectionism, economic nationalism resulting in government actions impacting international trade agreements or imposing trade restrictions such as tariffs and retaliatory counter measures.

A widespread public health crisis such as a pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity. In addition, a recession or market correction resulting from the effects of public health crises could materially affect our business and the value of our common stock. It may have further negative impacts, such as (a) a global or U.S. recession or other economic crisis; (b) credit and capital markets volatility (and access to these markets, including by our suppliers and customers); (c) manufacturing supply disruption due to travel restrictions or other government actions; (d) disruptions in raw material supply, our manufacturing operations, or in our distribution and supply chain; and (e) our ability to conduct planned clinical trials and commercialization activities. The ultimate impact of a public health crisis is highly uncertain.

Fluctuating interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

Vidya conducts certain research and development operations through a wholly-owned Australian subsidiary and benefits from the Australian Government's Research and Development Tax Incentive program. A reduction in, or loss of eligibility for, these incentives from the Australian government could increase our net cost of conducting research and development.

We have historically received cash incentives through the Australian Government's Research and Development Tax Incentive program, under which the Australian Government currently provides a refundable tax offset, payable as a cash incentive, for certain eligible approved research and development expenditures by Australian entities. Entitlement to tax offsets under the Research and Development Tax Incentive for eligible research and development purposes is based on an annual application to the Australian Government. For overseas activities with a significant scientific link to Australian activities, the expenditure in Australia must exceed the expected overseas expenditure to be eligible.

If our research and development expenditures are deemed "ineligible," our incentives would decrease and the net cost of conducting research and development would increase. In addition, our prior claims under the program remain subject to review by the Australian Taxation Office for up to four years after receipt. If any previously claimed expenditures are later determined to be ineligible, we could be required to repay some or all of the related incentive payments. The Australian Government may modify the requirements of, reduce the amounts of the tax offset entitlement under, or discontinue the Research and Development Tax Incentive program. If the Research and Development Tax Incentive program were discontinued, or if the tax incentive rate were reduced, it would negatively affect the size of future refundable tax offsets and our future cash flows. If our subsidiary loses its ability to operate in Australia, or if we are ineligible or unable to receive the research and development incentive payment, or the Australian government significantly reduces or eliminates the incentive program, our business and results of operation may be adversely affected.

Risks Related to the Development of our Product Candidates

Our development efforts are in the early stages. If we are unable to advance VT7208 or any other product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

There is no assurance that any clinical trials of VT7208, or any other product candidates we may develop will be successful or will generate positive clinical data and we may not receive marketing approval from the FDA or other regulatory agencies for any such product candidate. VT7208 is in the early stage of our development efforts, and if it, or any product candidate that we may develop, encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and forecasted timelines and business could be significantly harmed. We have completed a Phase 1 clinical trial of VT7208 in healthy volunteers and are planning Phase 2 clinical trials of VT7208 in food allergy and chronic spontaneous urticaria (CSU) expected to initiate in the second half of 2026, and a Phase 2 clinical trial of VT7208 in relapsing multiple sclerosis (MS) expected to initiate in the first half of 2027.

Biopharmaceutical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates. The success in the development of our product candidates will depend on many factors, including:

- initiating, enrolling, and completing clinical trials;
- submission of INDs for and receipt of allowance to proceed with our clinical trials or other future clinical trials;
- completing preclinical studies;
- obtaining positive results from our preclinical studies and clinical trials that support a demonstration of efficacy, safety, and durability of effect for our product candidates;
- receiving approvals for commercialization of our product candidates from applicable regulatory authorities;
- establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- manufacturing our product candidates at an acceptable cost and quality; and
- maintaining and growing an organization of scientists, medical professionals and business people who can develop and commercialize our product candidates and technology.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing and the regulatory submission process. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, or any other factors impacting the successful development of biopharmaceutical products, we could experience significant delays or an inability to successfully develop our product candidates, which could materially harm our business.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for VT7208 or any other product candidate we may develop, our business will be substantially harmed.

We do not have any products that have gained regulatory approval. Our business is substantially dependent on our ability to obtain and maintain regulatory approval for our development products, in particular VT7208. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA. Before obtaining regulatory approvals for the commercial sale of any product candidate for a particular indication, we must demonstrate with substantial evidence gathered in preclinical and clinical studies that the product candidate is safe and effective for that indication and that the manufacturing facilities, processes and controls are adequate to ensure sufficient product quality and control with respect to such product candidate. Prior to seeking approval for any of our product candidates, we will need to confer with the FDA and other regulatory authorities regarding the design of our clinical trials, the type and amount of clinical data necessary, the Chemistry, Manufacturing and Controls (CMC) requirements to seek and gain approval for our product candidates.

The time required to obtain approval by the FDA and other regulatory authorities is unpredictable and typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or other comparable regulatory authorities for many reasons, including:

- disagreement with the design, protocol or conduct of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a New Drug Application (NDA) or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes, or failure to obtain such approvals with respect to our facilities or the facilities of our contract manufacturing vendors;
- deficiencies in our CMC package, including inadequate characterization of the drug substance or drug product, insufficient control strategy, incomplete validation of manufacturing processes or analytical methods, or unresolved comparability, impurity, stability or specification issues, may delay or prevent approval;
- we may be unable to demonstrate that our manufacturing processes can be consistently scaled, validated and controlled to produce product candidates that meet applicable identity, strength, quality, purity and potency requirements;
- our analytical methods, release testing, reference standards or stability data may be insufficient to support product specifications, shelf life, storage conditions or commercial manufacturing approval;

- manufacturing facilities operated by us or our third-party manufacturers may fail to satisfy current good manufacturing practice (cGMP) requirements or may be subject to inspectional observations, warning letters, import alerts or other regulatory actions that could delay or prevent approval;
- changes in raw materials, suppliers, manufacturing sites, equipment, processes or specifications may require additional comparability, validation or bridging data and could result in delay in regulatory review or approval;
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval; or
- lack of adequate funding to complete a clinical trial in a manner that is satisfactory to the applicable regulatory authority.

Many of these risks are beyond our control, including the risks related to clinical development. If we are unable to develop, receive regulatory approval for, or successfully commercialize our product candidates, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

The FDA or a comparable regulatory authority may require more information, including additional preclinical or clinical data to support approval, including data that would require us to perform additional clinical trials or modify our manufacturing processes, controls, specifications, labeling, instructions or packaging, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. Further, if we change the primary or secondary endpoints in any of our clinical trials, either by our own choice or at the request of the FDA or a comparable regulatory authority, our development plans could be delayed, our costs could increase and our business could be materially harmed. If we change our manufacturing processes, we may be required to conduct additional clinical trials or other studies, which also could delay or prevent approval of our product candidates. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer indications than we request (including failing to approve the most commercially promising indications), may limit indications, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing commitments, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Even if a product candidate were to successfully obtain approval from the FDA or other comparable regulatory authorities in other jurisdictions, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product candidate or generate revenues attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn.

Our business is highly dependent on the success of VT7208. VT7208 will require additional clinical and manufacturing development before we are able to seek regulatory approval for and launch a product commercially and we may not be successful in our efforts.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We are devoting substantially all our resources to the development of VT7208 across our three initial target indications of food allergy, CSU and relapsing MS. Our existing clinical data for VT7208 is derived from a completed Phase 1 clinical trial in healthy volunteers involving single ascending dose (SAD) and multiple ascending dose (MAD) cohorts with 24 subjects. We are planning Phase 2 clinical trials in food allergy, CSU and relapsing MS. If VT7208, across the various target indications, encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and forecasted timelines and business could be significantly harmed. Because substantially all of our resources are concentrated on a single product candidate, any failure or significant delay in VT7208's development would have a disproportionate impact on our business, financial condition and prospects, and we do not have other clinical-stage programs that could offset such a setback.

We cannot provide you with any assurance that we will be able to successfully advance VT7208 or any additional product candidates through the development process in any particular target indication. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our product candidates may not succeed in preclinical or clinical testing;
- a product candidate may on further study be shown to have harmful side effects, or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our development program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which could have a material adverse effect on our business and could potentially cause us to cease operations.

If we do not successfully develop and commercialize product candidates or collaborate with others to do so, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect the trading price of our common stock.

If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, of sufficient purity and effective for use in each target indication, and failures can occur at any stage of testing. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication. A failure of one or more clinical trials can occur at any stage of testing. Any side effects or patient deaths could affect the development of our product candidates, even if deemed to not be drug related.

If any such adverse events occur, our clinical trials could be suspended or terminated. If we cannot demonstrate that any adverse events were not caused by the drug, the FDA or foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any of our product candidates, including:

- the FDA or other comparable regulatory authority may disagree as to the number, design or implementation of our clinical trials, or may not interpret the results from clinical trials as we do;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results;
- we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or abandon our product development programs;
- 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, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit suitable patients to participate in a trial;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA or other comparable regulatory authorities may fail to approve our manufacturing processes or facilities, or the facilities of our contract manufacturing vendors;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- deficiencies in our CMC package, including inadequate characterization of the drug substance or drug product, insufficient control strategy, incomplete validation of manufacturing processes or analytical methods, or unresolved comparability, impurity, stability or specification issues, may delay or prevent approval
- we may be unable to demonstrate that our manufacturing processes can be consistently scaled, validated and controlled to produce product candidates that meet applicable identity, strength, quality, purity and potency requirements;
- our analytical methods, release testing, reference standards or stability data may be insufficient to support product specifications, shelf life, storage conditions or commercial manufacturing approval;
- manufacturing facilities operated by us or our third-party manufacturers may fail to satisfy cGMP requirements or may be subject to inspectional observations, warning letters, import alerts or other regulatory actions that could delay or prevent approval;
- changes in raw materials, suppliers, manufacturing sites, equipment, processes or specifications may require additional comparability, validation or bridging data and could result in delay in regulatory review or approval;

- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the clinical trials; and
- the approval policies or regulations of the FDA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

To the extent that the results of the trials are not satisfactory for the FDA or regulatory authorities in other countries or jurisdictions to approve our NDAs or other comparable applications, the commercialization of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

Clinical trials are difficult to design and implement, can be lengthy and expensive, involve uncertain outcomes and may not ultimately be successful.

It is impossible to predict when or if any of our current or future product candidates will prove effective and safe in humans or will receive regulatory approval. 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. Human clinical trials are expensive, can take many years to complete, and are difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. There is a high failure rate for autoimmune disease product candidates proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Negative outcomes or data integrity failures by competitors in the autoimmune disease space could adversely affect our business, reputation, and the regulatory and commercial environment in which we operate.

The clinical and commercial success of VT7208 may be influenced not only by our own data and results, but also by the outcomes and perceived integrity of data generated by competitors operating in the same therapeutic area. If a competitor's product or product candidate is withdrawn from the market, subject to a safety recall, or associated with serious adverse events, whether in clinical trials or following regulatory approval, patients, physicians, payers, and the broader medical community may develop a generalized skepticism or loss of confidence in the underlying treatment modality or target mechanism. This loss of confidence could reduce patient enrollment in our clinical trials, dampen physician adoption of our products, or cause payers to impose more restrictive coverage and reimbursement policies, regardless of whether our products share the specific deficiencies identified in the competitor's product.

In particular, hepatotoxicity seen in the Bruton's tyrosine kinase (BTK) inhibitor class could adversely affect perceptions of VT7208. Evobrutinib and fenebrutinib were each placed on partial clinical hold following cases of liver-enzyme elevation, and the development of tolebrutinib, despite receiving approval from the European Medicines Agency (EMA) in progressive MS, has likewise been impacted by hepatic safety findings. These prior hepatic safety events may cause regulators, physicians, patients and investors to apply heightened scrutiny to VT7208. There can be no assurance that VT7208 will not encounter similar safety issues in larger or longer clinical trials or that the class-wide perception of hepatic risk will not impair our ability to enroll patients, attract investigators, obtain regulatory approval or achieve commercial acceptance. If VT7208 is unable to differentiate itself from the hepatotoxicity profile associated with other members of the BTK inhibitor class, or if additional adverse hepatic events are reported by competitors developing BTK inhibitors for autoimmune indications, our business, financial condition, results of operations and prospects could be materially adversely affected.

We have no control over the research, development, manufacturing, or commercial practices of our competitors in the autoimmune disease space, and we cannot predict whether their data or products will meet the standards expected by regulators, the medical community, or the public. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. For example, we are currently focusing the majority of our efforts on the development of VT7208, and specifically for the clinical indications of food allergy, CSU and relapsing MS. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. 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. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

Success in preclinical studies or clinical trials may not be predictive of results in future clinical trials.

Results from preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials are not necessarily predictive of final results. We do not know whether our candidates will be effective for the intended indications or safe in humans. Our product candidates may fail to show the desired safety and efficacy in preclinical or clinical development despite positive results observed in early preclinical studies or having successfully advanced through initial clinical trials. Any failure to establish sufficient efficacy and safety could cause us to abandon clinical development of our product candidates. Further, our clinical trials to date have involved small patient populations. Because of the small sample sizes, the results of these trials may not be indicative of results of future clinical trials.

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

We expect to publish from time to time interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. 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 topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval or commercialization of the particular product candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Since the number of patients that have been and will be dosed in our completed Phase 1 clinical trial of VT7208 is small, the results from such clinical trial may be less reliable than or may not be predictive of results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for VT7208.

The preliminary results of clinical trials with smaller sample sizes can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the characteristics of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. Our completed Phase 1 clinical trial of VT7208 enrolled 24 healthy volunteers. The small number of subjects enrolled in this trial limits the statistical power of our results and increases the potential for any individual subject outcome to disproportionately influence our overall findings. As a result, there may be less certainty that VT7208 would achieve a statistically significant effect in any future clinical trials in patient populations. Further, there can be no assurance that the results observed in our Phase 1 trial will be replicated in patient populations across these indications. The planned Phase 2 trials will enroll patient populations with distinct disease characteristics, and VT7208 may not demonstrate the safety, tolerability, or efficacy profile necessary to support further clinical development in one or more of these indications. If those results are not indicative of data that would be generated in larger clinical trials, our assumptions in support of our clinical development activities may prove to be inaccurate and the FDA or other comparable regulatory authorities may require us to conduct additional and larger clinical trials than we currently plan.

If we conduct any future clinical trials of VT7208 or our other product candidates, we may not achieve a positive or statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on prior results from our completed or ongoing trials. Such failure could hinder our efforts to obtain regulatory approval for VT7208 or our other product candidates.

The comparisons we present regarding VT7208's safety and efficacy profile relative to other BTK inhibitors are subject to significant limitations and may not be predictive of VT7208's relative performance in future controlled studies.

Herein, and in our other public communications, we present data comparing VT7208's pharmacokinetics, emerging preclinical profile and predicted drug-induced liver injury risk score to other BTK inhibitors, including tolebrutinib and remibrutinib. These comparisons are derived from preclinical studies of VT7208 and conducted against these other BTK inhibitors. Outside of the preclinical head-to-head studies, no head-to-head clinical trials have been conducted comparing VT7208 to any other BTK inhibitor, and cross-trial comparisons are inherently limited and may not accurately reflect the relative safety or efficacy of the agents being compared. The results of any preclinical head-to-head studies may not be predictive of relative CNS exposure in humans. Any published data from the clinical trials of these other BTK inhibitors are from trials conducted at different times, with differences in trial design, patient populations, disease settings, dosing regimens, endpoints, sample sizes, follow-up periods, and adverse event grading criteria from the clinical trials for VT7208. Physicians, patients, investors, and regulatory authorities may draw conclusions from cross-trial comparisons that are not supported by the underlying data or may discount VT7208's potential based on the inherent limitations of such comparisons. In particular, comparisons based on published results from a competitor may become outdated if such competitor generates additional clinical data. If VT7208's clinical profile does not compare as favorably to other BTK inhibitors as our preclinical analyses suggest, or if our hepatotoxicity differentiation claims are not borne out in clinical studies, the commercial prospects and perceived differentiation of VT7208 could be materially diminished.

We depend on timely enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the number of patients with the disease or condition being studied;
- the perceived risks and benefits of the product candidate in the trial;
- 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 we are investigating or drugs that may be used off-label for these indications;
- clinicians' and patients' perceptions as to any risks associated with our competitors' product candidates;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion of their treatment;
- factors we may not be able to control, such as pandemics, that may limit patients, principal investigators or staff or clinical sites available;
- delays in activating clinical trial sites, including delays related to site contracting, budgeting, institutional review board or ethics committee approvals, training or initiation activities;
- high screen failure rates, including as a result of narrow eligibility criteria, required diagnostic confirmation or other protocol-specific requirements;
- competition from approved therapies, standard-of-care alternatives or other treatment options that may reduce patients' willingness to enroll in our clinical trials;
- the burden on patients participating in our clinical trials, including visit frequency, travel requirements, monitoring obligations, procedures, follow-up requirements or other protocol-related demands;
- the availability of specialized testing, biomarkers or diagnostic tools needed to identify or confirm eligible patients;
- our ability to enroll a sufficiently diverse and representative patient populations across demographics, disease characteristics or geographies to support regulatory review;

- patient retention, protocol adherence and timely completion of trial visits and procedures, including missed visits, noncompliance or withdrawal of consent; and
- site staffing constraints, investigator turnover or limited clinical trial infrastructure.

In addition, because the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these clinical trial sites.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our projections of addressable market opportunity for VT7208 are based on estimates and assumptions that may prove incorrect, and the actual commercial opportunity may be substantially smaller than we expect.

We have made internal estimates of the total addressable market for VT7208 and other product candidates targeting the BTK pathway, including estimates of patient populations, treatment penetration rates, and potential pricing. These estimates are based on a variety of sources, including published scientific literature, epidemiological data, market research and our own calculations and assumptions about competitive dynamics. However, these estimates are inherently uncertain and may prove to be materially incorrect.

The actual addressable market for VT7208 may be smaller than we estimate for several reasons, including: the prevalence of food allergy, CSU or MS in the populations we are targeting may be lower than published estimates suggest, or the proportion of patients within those populations for whom BTK inhibition is an appropriate treatment may be more limited than we project, and our efforts to estimate the potential market opportunity for food allergy and CSU is particularly challenging given that treatment options are very early in their approval by the FDA and adoption by patients and providers; physicians may not adopt VT7208 over established therapies; payors may restrict reimbursement; VT7208 may initially be approved only for later-line treatment settings with smaller patient populations; competing products may capture significant market share before VT7208 reaches the market; and advances in autoimmune disease therapies may further segment the patient population. If the actual market opportunity for VT7208 is materially smaller than our estimates, we may not be able to generate sufficient revenue to justify our development investment, which could have a material adverse effect on our business and financial condition.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, cause us to abandon product candidates, could limit the commercial profile of an approved label, or could result in significant negative consequences following any potential marketing approval.

Our clinical trials will include patients suffering from autoimmune diseases, including food allergy, CSU and relapsing MS. It is possible that some of these patients may experience side effects during our clinical trials. Further, BTK inhibitors, including approved and investigational agents such as ibrutinib, acalabrutinib, tolebrutinib, evobrutinib, fenebrutinib, and remibrutinib, have been associated with adverse events including hepatotoxicity (including elevated liver enzymes and drug-induced liver injury), bleeding events (including mucocutaneous bleeding), infections (including opportunistic infections, upper respiratory tract infections, urinary tract infections, and reactivation of latent viral infections), neutropenia, thrombocytopenia, atrial fibrillation, hypertension, diarrhea, nausea, rash, arthralgia, headache, fatigue, and tumor lysis syndrome. Certain BTK inhibitors have also been associated with serious hepatic events, including cases that have led to clinical holds, labeling restrictions, or regulatory delays. For example, evobrutinib and fenebrutinib were each placed on partial clinical hold following cases of liver-enzyme elevation, and the development of tolebrutinib was likewise impacted by hepatic-safety findings. We cannot be certain that hepatic or other toxicity will not occur with the evaluation of VT7208. While we did not observe any serious adverse events, or any hepatic safety events in our Phase 1 trial, our data are limited by a small sample size, limited drug exposure and treatment of healthy volunteers, and there remains a risk that serious adverse events may be uncovered in clinical trials with greater sample sizes, prolonged exposure to VT7208 or patient populations with distinct disease characteristics. Further, there can be no assurance that the tolerability profile observed in our preclinical studies will translate to a comparable profile in humans. This risk may be of particular significance given that our Phase 1 trial enrolled only healthy volunteers and our planned Phase 2 trials will be the first evaluation of VT7208 in patient populations who may respond differently to BTK inhibition. If these or other adverse effects occur with unacceptable frequency or severity in our clinical trials, our ability to develop and commercialize VT7208 could be materially impaired. In particular, while several BTK inhibitors have been approved for oncology indications, we believe the FDA and comparable foreign regulatory authorities may apply a different risk-benefit threshold for VT7208 for the treatment of chronic autoimmune diseases such that any harmful side effects that may outweigh the benefits of our product candidate would require us to cease clinical trials or abandon or limit our development of VT7208 or would cause the FDA or comparable foreign regulatory authorities to deny marketing applications for VT7208 for chronic autoimmune indications. Accordingly, the risks of negative impact from BTK inhibitors may therefore be higher for our autoimmune programs than for the oncology programs of others. Further, patients may die during our clinical trials for various reasons. The causes of death could include receiving our product candidates because the patient's disease is too advanced or because the patient experiences medical problems that may not be related to our product candidate. Even if the patient deaths are not related to our product candidate, the deaths could affect perceptions regarding the safety of our product candidates. Patient deaths and severe side effects caused by our product candidates, or by products or product candidates of other companies that are thought to have similarities with our product candidates, could result in the delay, suspension, clinical hold or termination of our clinical trials, by the FDA or other regulatory authorities for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates would be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such products;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to create a Risk Evaluation and Mitigation Strategy (REMS) plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may decide to remove such products from the marketplace;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

We are targeting chronic autoimmune diseases across multiple distinct indications, which presents additional risks with respect to clinical development, regulatory approvals and commercialization of product candidates.

Our approach of targeting chronic autoimmune diseases, including food allergy, CSU and relapsing MS, presents risks related to the clinical development, regulatory approval and commercialization of our product candidates. We are pursuing three distinct indications simultaneously, each with its own patient population, disease biology, regulatory pathway and competitive landscape, which increases the complexity of our development program and the likelihood that setbacks in one indication could divert resources from or create negative perceptions regarding the others. Additional risks include the following:

- because the autoimmune conditions we are targeting are chronic, non-life-threatening diseases that may require treatment for years or decades, we must demonstrate a safety and tolerability profile suitable for long-term use, which represents a significantly higher bar than is typically required in acute or oncologic settings where greater toxicity may be tolerated in exchange for survival benefit. The prior development of other BTK inhibitors in autoimmune indications has been impeded by tolerability limitations, particularly hepatotoxicity, and regulators, physicians and patients may apply heightened scrutiny to VT7208 as a result;
- each of our target indications presents distinct clinical heterogeneity that may complicate trial design and interpretation of results. Food allergy involves considerable variability in symptomatic presentation, ranging from mild reactions to life-threatening anaphylaxis. MS encompasses multiple disease subtypes, including relapsing, secondary progressive and primary progressive forms, each with different pathophysiology, natural history and treatment response profiles. This heterogeneity may make it more difficult to design trials that yield statistically significant and clinically meaningful results across our target populations;
- we may face challenges with respect to patient enrollment in our clinical trials, particularly given that we are conducting trials across three distinct indications simultaneously, which may strain our operational resources and limit our ability to recruit sufficient patients at each clinical trial site, as described above;
- our clinical data to date are derived from a Phase 1 trial of 24 healthy volunteers, and our planned Phase 2 trials will involve relatively small sample sizes, which increases the risk of substantial variability in results and reduces the likelihood that outcomes from early-stage trials will be predictive of the success of later-stage, larger clinical trials in patient populations;
- following approval of our product candidates, if any, pricing and level of reimbursement may not be sufficient to offset costs of development, manufacturing, marketing, and commercialization;
- we may have difficulty selecting, validating and achieving clinically meaningful endpoints that are acceptable to regulatory authorities, particularly given that our three target indications use different primary endpoints and outcome measures, and we are relying in part on biomarker and challenge-based endpoints in food allergy and magnetic resonance imaging (MRI)-based endpoints in MS that may not be accepted by regulators as adequate for approval;
- we may have difficulty in accurately diagnosing, stratifying or confirming patients with food allergy, CSU or MS, which could adversely affect enrollment, clinical trial design and interpretation of results. In particular, identifying and confirming immunoglobulin E (IgE)-mediated food allergy requires allergen-specific testing and oral food challenges, and stratifying MS patients across relapsing and progressive subtypes requires careful clinical and radiographic assessment;
- regulatory authorities may require larger, longer, additional or different clinical trials than we anticipate, including studies in specific subpopulations or trials designed to address particular safety, efficacy or dosing questions; and
- while the overall patient populations for food allergy, CSU and MS are substantial, the subset of patients within each indication who are appropriate candidates for a BTK inhibitor, and specifically for VT7208, may be smaller than we estimate, and the competitive landscape in each indication is evolving rapidly as other therapies, including other BTK inhibitors, may reach the market ahead of VT7208.

Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with product candidates we may develop, are based on estimates. These estimates have been derived from a variety of sources, including published scientific literature, epidemiological data, patient advocacy groups and market research. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. For example, estimates of the prevalence of IgE-mediated food allergy, the number of CSU patients who remain symptomatic despite antihistamine therapy, and the proportion of MS patients with progressive disease may all prove to be different from our assumptions. The number of patients in the United States, Europe and elsewhere may turn out to be lower than expected, and patients may be more difficult to identify and access than our estimates contemplate.

Adverse developments with respect to any of the foregoing could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations, and prospects.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of any other product candidate we develop.

Any product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations (CROs) or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues may be materially impaired.

Risks Related to Development and our Dependence on Third Parties

We currently rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such clinical trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates.

We currently rely on third-party CROs, academic institutions, study sites, clinical investigators and others to conduct, supervise, and monitor our preclinical studies and clinical trials. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we currently have or plan to enter into agreements governing the activities of these third parties, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to develop VT7208 and other current and future product candidates, or we may not obtain marketing approval for, or commercialize, VT7208 or our other current and future product candidates in a timely manner or at all.

Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements our product development activities could be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our reliance on these third parties for development activities reduces our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical studies are conducted in accordance with the FDA's Good Laboratory Practice (GLP) regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with Good Clinical Practices (GCPs) 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 of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not our employees, and except for remedies available to us under our agreements with such third parties we cannot control whether or not they devote sufficient time and resources to the development of our product candidates. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if these parties are adversely impacted by a pandemic limiting or materially affecting their ability to carry out their contractual duties, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for current and future product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize current and future 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 current and future product candidates may be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

We may enter into collaborations for our current or future product candidates or technologies. We cannot control the timing or quantity of resources that our existing or future collaborators will dedicate to research, preclinical and clinical development. Our collaborators may not perform their obligations according to our expectations or standards of quality. Our collaborators could terminate our existing agreements for a number of reasons, many of which may be beyond our control.

We will also rely on other third parties to store and distribute our product candidates for the clinical trials that we plan to conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of current and future product candidates, which could result in additional losses and deprive us of potential product revenue.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management's time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We currently rely on CMOs for the production of VT7208, and we expect to rely on CMOs for our other product candidates. This reliance on CMOs increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies 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 currently have no plans to build our own clinical or commercial-scale manufacturing capabilities for our product candidates. Instead, we expect to rely on third parties for the manufacture of our product candidates and related raw materials for future preclinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. We have entered into arrangements with a limited number of third-party contract manufacturing organizations (CMOs) as part of our development of our product candidates. These CMOs will provide drug substance intermediate, device, and drug product that will be subsequently, tested, released, labeled, packaged and distributed to our CROs. We may also enter into agreements with additional companies for the supply of substances for use in the development of our product candidates or any future product candidates or for the manufacture of such product candidates.

We or our third-party suppliers or manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredient (API) necessary to produce product candidates in the quantities needed for our clinical trials or, if any current or future product candidates we may develop are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or API, including shortages caused by the purchase of such raw materials or API by our competitors or others. Even if raw materials or API are available, we may be unable to obtain sufficient quantities at an acceptable cost or quality. The failure by us or our third-party suppliers or manufacturers to obtain the raw materials or API necessary to manufacture sufficient quantities of any current or future product candidates we may develop could delay, prevent or impair our development efforts and may have a material adverse effect on our business.

The facilities used by third-party manufacturers to manufacture current or future product candidates must be authorized by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of drug products and other laws and regulations. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

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. Although we do not intend to begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, 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 any of our product candidates. Additionally, any changes implemented by a new CMO would require substantial investment to qualify and validate the vendor as a suitable third party manufacturer of our development or marketed products. Furthermore, we may be required to conduct comparability assessments, which may include additional human clinical studies, in conjunction with validating the new CMO(s).

If any CMO with whom we contract fails to perform its obligations, it could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our current and future product candidates and jeopardize our ability to commence product sales and generate revenue.

If any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials or commercial supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidates that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates or products. In addition, in the case of CMOs that supply our product candidates, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

As part of their manufacture of our product candidates, our CMO and third-party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If our CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes, misappropriates or otherwise violates the intellectual property or 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 applicable claims, either of which could significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, we may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms.

Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;

- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- production difficulties caused by unforeseen events that may delay the availability of one or more of the necessary raw materials or delay the manufacture of any current or future product candidates for use in clinical trials or for commercial supply;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Any product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time-consuming to implement. We do not currently have arrangements in place for redundant supply or second sources of supply with alternative suppliers or CMOs to supplement or supply the raw materials, drug substances, intermediates, and drug product necessary for the manufacture of our product candidates, including VT7208. If our current third-party CMO cannot perform as agreed, we may be required to replace such manufacturer and we may be unable to replace them on a timely basis or at all.

Because we rely on a single supplier for our drug substance, and a limited number of suppliers for the raw materials used in our drug candidates, any delay, shortage or interruption in the supply of such raw materials or contamination in our manufacturing process could lead to delays in the manufacture and supply of our drug candidates.

We rely on third parties to supply certain raw materials necessary to produce our drug candidates for preclinical studies and clinical trials. For example, BioDuro is currently our single supplier for our drug substance. If BioDuro were unable or unwilling to supply the drug substance to us, we would need to identify an alternative supplier, which would require significant time and expense; however, we believe we could source an alternative supplier if needed. There are a small number of suppliers for certain raw materials that we use to manufacture our drug candidates. Certain of our suppliers or their sub-suppliers are based in China, which exposes us to additional risks including trade restrictions, tariffs, export controls, geopolitical tensions, and potential disruptions to the supply chain that are beyond our control. We work with our CMOs to purchase these materials from our suppliers who may not always have long-term supply agreements in place, which could expose us to a variety of risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to our contract manufacturing caused by problems at suppliers could delay shipment of our product candidates, increase our cost of goods sold and result in lost sales with respect to any approved products. Any significant delay in the supply of raw materials for our drug candidates for a preclinical study or a clinical trial due to the need to replace a third-party supplier could considerably delay completion of certain preclinical studies and/or clinical trials. Moreover, if we are unable to purchase sufficient raw materials after regulatory approval for our drug candidates, the commercial launch of our drug candidates could be delayed, or there could be a supply shortage, each of which could impair our ability to generate revenues from their sale.

In addition, a material shortage, contamination, recall or restriction on the use of substances in the manufacture of our drug candidates, or the failure of any of our key suppliers to deliver necessary components required for the manufacture of our drug candidates, could adversely impact or disrupt the commercial manufacture or the production of clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations, and future prospects.

Third parties upon which we rely for preclinical and clinical studies may become the subject or target of certain sanctions or restrictions, which may have adverse effects on our operations and business.

Certain foreign contract manufacturing organizations (CMOs) and biotechnology companies may become subject to legislation, trade restrictions, sanctions, tariffs, and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities. The BIOSECURE Act, which was signed into law in December 2025 as part of the National Defense Authorization Act for Fiscal Year 2026, prohibits U.S. federal agencies from entering into or renewing any contract, loan, or grant with any entity that uses biotechnology equipment or services produced or provided by a “biotechnology company of concern” to perform that contract. The Office of Management and Budget (OMB) of the U.S. Government will issue a list of “biotechnology companies of concern,” which will include certain companies that are identified on the U.S. Department of Defense’s annual List of Chinese Military Companies, also known as the 1260H List, other entities which the U.S. Government has deemed as such pursuant to a separate designation process, and certain subsidiary, parent, and successor entities of the foregoing. The BIOSECURE Act includes a grandfathering provision providing that the prohibitions shall not apply for a five-year period to biotechnology equipment or services produced or provided under a contract or agreement entered into before the applicable effective date. If any of our third party CMOs or service providers are designated as “biotechnology companies of concern” by OMB, we may be restricted in our ability to work with such companies to the extent we would contract with, or otherwise receive funding from, the U.S. government. As a result, we may need to seek alternative relationships. While we believe we will be able to identify and contract with such alternative vendors, we cannot guarantee that alternative vendors with the necessary capabilities and capacity would be available on a timeline that would not materially delay the development of our therapeutic candidates and cannot predict the terms of any such alternative arrangement nor what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by China or the other countries in retaliation. In addition, any unfavorable government policies on international trade, such as export controls, tariffs, new legislation, renegotiation of existing trade agreements, or any retaliatory trade actions due to recent or future trade tension, may impede, delay, limit, or increase the cost of manufacturing our therapeutic candidates.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Regulatory Approval of our Product Candidates and Other Legal Compliance Matters

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize or will be delayed in commercializing our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates, we must obtain marketing approval. Currently, all of our product candidates are in development, and we have not received approval to market any of our product candidates, including VT7208 for the treatment of food allergy, CSU and relapsing MS, from regulatory authorities in any jurisdiction. It is possible that our product candidates, including any product candidates we may seek to develop in the future, will never obtain regulatory approval. Whether the results from our clinical trials will suffice to obtain approval will be a review issue and the FDA may not grant approval and may require that we conduct one or more additional controlled clinical trials to obtain approval. Additionally, even if the FDA does grant approval for one or more of our product candidates, it may be for a more narrow indication than we seek. Regulatory authorities, including the FDA, also may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions or contraindications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we may develop.

We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. In addition, regulatory authorities may find fault with our manufacturing process or facilities or that of third-party contract manufacturers. We may also face greater than expected difficulty in manufacturing our product candidates.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive and often takes many years. If the FDA or a comparable foreign regulatory authority requires that we perform additional preclinical studies or clinical trials, approval, if obtained at all, may be delayed. The length of such a delay varies substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted NDA, premarket approval application, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our preclinical studies or clinical trials;
- we may not be able to enroll a sufficient number of patients in our clinical studies;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change such that our clinical data are insufficient for approval.

Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, thereby narrowing the commercial potential of the product candidate. In addition, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

We may submit marketing applications in countries other than the United States. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In short, the foreign regulatory approval process involves all of the risks associated with FDA approval. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we may intend to charge for our products will also be subject to approval.

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 post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, storage, advertising, promotion, import, export, recordkeeping, monitoring, and reporting for our product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product.

The FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- revision to the labeling, including limitations on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which could adversely affect our business, prospects and ability to achieve or sustain profitability.

Our relationships with customers, healthcare professionals, and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to significant penalties, including criminal sanctions, administrative civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Our current and future business operations and activities may subject us to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute our product candidates for which we obtain marketing approval. These laws and regulations may restrict or prohibit a wide range of ownership, pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities 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. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal civil and criminal false claims, including the federal False Claims Act (FCA), which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;
- Health Insurance Portability and Accountability Act (HIPAA), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal physician payment transparency requirements, sometimes referred to as the “Sunshine Act” under the Affordable Care Act (ACA) require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report to the Centers for Medicare & Medicaid Services (CMS) information related to transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as nurse practitioners and physicians assistants), and teaching hospitals, as well as information regarding ownership and investment interests of such physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and its implementing regulations, impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Some state and local laws require certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales representatives. Further, many state laws governing the privacy and security of health information in certain circumstances, differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including compensation of physicians with stock or equity awards, could, despite efforts to comply, be subject to challenge under current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were to be 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, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, integrity oversight and reporting obligations, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current or future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (the OBBBA) was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at the U.S. Department of Health and Human Services (HHS), the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with certain pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform (TrumpRx), U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on certain imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on June 15, 2026, the FDA approved Colorado's Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this and Florida's similar program, approved by the FDA in 2024, will be implemented and whether they will overcome potential legal, regulatory, or industry challenges in the United States and/or Canada. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We are subject to the Bribery Act, the FCPA, and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010 (the Bribery Act), the Foreign Corrupt Practices Act of 1977, as amended (FCPA), the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The Bribery Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. Compliance with Trade Control laws may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, Trade Control laws prohibit the provision of certain products and services to countries, governments and persons targeted by sanctions.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by United Kingdom, United States or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations may also produce hazardous waste products. We generally intend to contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Commercialization of our Product Candidates

If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if approved.

We have never commercialized a product. To achieve commercial success for any product for which we obtain marketing approval, we will need a sales and marketing organization and establish logistics and distribution processes to commercialize and deliver our product candidates to patients and healthcare providers. We currently plan to work to build our commercialization capabilities internally over time such that we are able to commercialize any product candidate for which we may obtain regulatory approval. However, we currently have no sales, marketing or distribution capabilities and have no experience in marketing or distributing pharmaceutical products. These activities will be expensive and time-consuming and will require significant attention of our executive officers to manage. There are risks involved in establishing our own sales and marketing capabilities, as well as with entering into arrangements with third parties to perform these services. Additionally, our beliefs that our products will be commercially viable have not been tested.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we would have to pursue collaborative arrangements regarding the sales and marketing of our products. However, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us, or if we are able to do so, that they would be effective and successful in commercializing our products. Our product revenues and our profitability, if any, would likely to be lower than if we were to sell, market and distribute any product candidates that we develop ourselves. In addition, we would have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates, including VT7208, effectively.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates in the United States or overseas.

We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid and significant technological advancements. We face competition from major multi-national pharmaceutical companies, biotechnology companies and specialty pharmaceutical companies with respect to our current and future product candidates that we may develop and commercialize in the future. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of autoimmune diseases, including food allergy, CSU and relapsing MS. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Potential competitors also include academic institutions, government agencies and other public and private research organizations.

Remibrutinib, sold by Novartis, is an approved BTK inhibitor for the treatment of CSU, and Xolair (omalizumab), sold by Genentech/Roche, is approved for CSU and food allergy. We are aware of several product candidates in clinical development for the treatment of our target indications, including BTK inhibitors and other approaches. In CSU, we are aware of competitors including Celldex (barzolvolimab), Jasper (briquilimab), Sanofi/Regeneron (dupilumab), Septerna (SEP-631), Sanofi (blu-808), and others. In food allergy, we are aware of competitors including Novartis (remibrutinib), DBV Technologies (Viaskin Peanut), ALK-Abelló (peanut sublingual immunotherapy (SLIT) tablet), RAPT/GSK (ozureprubart), and others. In MS, we are aware of competitors including Sanofi (tolebrutinib), Roche/Genentech (fenebrutinib), Novartis (remibrutinib), Zenas (orelabrutinib), Immunic (vidofludimus calcium), and AB Science (masitinib). Several of these product candidates are in Phase 3 registrational trials with potential approval timelines that are ahead of our development timeline for VT7208, including Roche's fenebrutinib in Phase 3 for primary progressive MS (PPMS) and Novartis's remibrutinib in Phase 3 for non-relapsing secondary progressive MS (nrSPMS). In addition, we are aware of approved therapies that are used in certain of our target patient populations, including therapies manufactured by Genentech/Roche, Novartis, Sanofi, and others.

Our competitors with development-stage programs may obtain marketing approval from the FDA or other comparable regulatory authorities for their product candidates more rapidly than we do, and they could establish a strong market position before we are able to enter the market. In addition, our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective, more effectively marketed and sold or less costly than any product candidates that we may develop, which could render our product candidates non-competitive and obsolete. Because of our primary focus on autoimmune diseases, if our product candidates achieve marketing approval, we expect to seek premium pricing.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

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

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if we obtain approvals from the FDA or other comparable regulatory agencies and are able to initiate commercialization of our product candidates or any other product candidates we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;

- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage, adequate reimbursement from, and our ability to negotiate pricing with, third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts and distribution support.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates, if approved, may require significant resources and may never be successful. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance could harm our business and could require us to seek additional financing.

Even if our product candidates, if approved, achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates, if approved, that we commercialize will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, one payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment will be approved. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may incur significant costs to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor's formulary generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, and providers are unlikely to prescribe our products, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products and their administration. Therefore, coverage and adequate reimbursement is critical to new medical product acceptance.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years and biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Moreover, our positioning of VT7208 as a treatment option in indications where multiple therapies already exist, including both approved and investigational BTK inhibitors such as ibrutinib, may limit our pricing power and reimbursement potential, as third-party payors may view VT7208 as an incremental addition to existing treatment options and may impose step therapy, prior authorization or other access restrictions. Physicians may also be reluctant to prescribe a new agent in patient populations where polypharmacy risks are heightened or until the product profile is well established.

Our business, operational and financial goals may not be attainable if the market opportunities for our products are smaller than we expect. Our internal research and third-party estimates may not accurately reflect the market opportunities for VT7208 or our other product candidates today or in the future.

The total market opportunities that we believe exist are based on a variety of assumptions, calculations and estimates, including the size of the addressable patient population in applicable jurisdictions, the penetration of other drugs in these markets, the number of patients we will test in clinical trials, the price we will be able to charge for our products and the total annual number of patients with food allergy, CSU or MS. In addition, we have relied on third-party publications, research, surveys and studies for information related to determining market opportunities, including without limitation, information on the number of autoimmune disease patients and those receiving various forms of treatment, the cost of drug therapy, the amount of revenue generated from various types of drug therapy, the number of deaths or severe outcomes caused by food allergy, CSU or MS, and the expected growth in related drug therapy and diagnostic markets. Our internal research and estimates on market opportunities include the use of independent sources, but any or all of our assumptions and/or estimates may prove to be incorrect for several reasons, such as inaccurate reports or information that we have relied on, potential patients or providers not being amenable to using our products or such patients becoming difficult to identify and access, limited reimbursement for our products, pricing pressure due to availability of alternative drugs or an inability to obtain the necessary regulatory approvals for new indications. If any or all of our assumptions and estimates prove inaccurate, we may not attain our business, operational and financial goals.

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

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

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

Risks Related to our Digital Asset Treasury Strategy

Investments in Digital Assets are substantially speculative and have a significant risk of resulting in a loss compared to other forms of investment.

While all investments entail a risk of loss of capital, investments in digital assets such as Chiliz (CHZ) and other cryptocurrencies, tokens, and rights of a similar nature (collectively referred to as, Digital Assets) should be considered substantially more speculative and significantly more likely to result in a loss, including a total loss of capital, than many other forms of investment. The investment characteristics of Digital Assets differ from those of many traditional currencies, commodities, and securities. A particular Digital Asset's status as a "security" in any relevant jurisdiction is subject to a high degree of uncertainty, and if we are unable to properly characterize a Digital Asset, we may be subject to regulatory scrutiny, investigations, fines, and other penalties, which may adversely affect our business, results of operations and/or financial condition.

The legal test for determining whether any given Digital Asset is a security is a highly complex, fact-driven analysis and the outcome is difficult to predict. The SEC generally does not provide advance guidance or confirmation on the status of any particular asset as a security. The classification of a Digital Asset as a security under applicable law has wide-ranging implications for the regulatory obligations that flow from the offer, sale and trading of such assets. For example, a Digital Asset that is a security in the United States may generally only be offered or sold in the United States pursuant to a registration statement filed with the SEC or in an offering that qualifies for an exemption from registration. Persons that effect transactions in assets that are securities in the United States may be subject to registration with the SEC as a "broker" or "dealer." Platforms that bring together purchasers and sellers to trade Digital Assets that are securities in the United States are generally subject to registration as national securities exchanges, or must qualify for an exemption, such as by being operated by a registered broker-dealer as an alternative trading system (ATS), in compliance with rules for ATSs. Persons facilitating clearing and settlement of securities may be subject to registration with the SEC as a clearing agency. Foreign jurisdictions may have similar licensing, registration, and qualification requirements. As a result, certain Digital Assets may be deemed to be a "security" under the laws of some jurisdictions but not others. Further, various foreign jurisdictions may, in the future, adopt additional laws, regulations, or directives that affect the characterization of Digital Assets as "securities."

We could be subject to legal or regulatory action in the event the SEC, a foreign regulatory authority, or a court were to determine that a digital asset held by us is a "security" under applicable laws.

Digital Assets have historically experienced, and are expected to continue to experience, high price volatility which may influence our financial results and the market price of our common stock.

Digital Assets have historically experienced, and are expected to continue to experience, high price volatility. Such price fluctuations are likely to influence our financial results and the market price of our common stock. Our financial results and the market price of our common stock would be adversely affected, and our business and financial condition would be negatively impacted, if the price of Digital Assets we hold decrease substantially, including as a result of:

- decreased user and investor confidence in Digital Assets, including due to the various factors described herein;
- investment and trading activities, such as (i) trading activities of highly active retail and institutional users, speculators, miners and investors, (ii) actual or expected significant dispositions of digital assets by large holders, and (iii) actual or perceived manipulation of the spot or derivative markets for digital assets;
- negative publicity, media or social media coverage, or sentiment due to events in or relating to, or perception of, Digital Assets or the broader Digital Assets industry;
- changes in consumer preferences and the perceived value or prospects of Digital Assets;
- competition from other Digital Assets that exhibit better speed, security, scalability, or energy efficiency, that feature other more favored characteristics, that are backed by governments, including the U.S. government, or reserves of fiat currencies, or that represent ownership or security interests in physical assets;
- disruptions, failures, unavailability, or interruptions in service of trading venues for Digital Assets;
- the filing for bankruptcy protection by, liquidation of, or market concerns about the financial viability of digital asset custodians, trading venues, lending platforms, investment funds, or other Digital Asset industry participants;
- regulatory, legislative, enforcement and judicial actions that adversely affect the price, ownership, transferability, trading volumes, legality or public perception of Digital Assets, or that adversely affect the operations of or otherwise prevent digital asset custodians, trading venues, lending platforms or other Digital Assets industry participants from operating in a manner that allows them to continue to deliver services to the Digital Assets industry;
- macroeconomic changes, such as changes in the level of interest rates and inflation, fiscal and monetary policies of governments, trade restrictions, and fiat currency devaluations; and
- developments in mathematics or technology, including in digital computing, algebraic geometry and quantum computing, that could result in the cryptography used by the digital asset blockchain becoming insecure or ineffective.

We may be unable to successfully implement our Digital Asset Strategy.

Our Digital Asset treasury reserve strategy has only been recently approved by our Board. There is no assurance that we will be able to successfully implement this new strategy or operate Digital Asset-related activities at the scale or profitability currently anticipated. Successfully implementing this strategy may present organizational and infrastructure challenges, and we may not be able to fully implement or realize the intended benefits of our strategy. There can be no assurance that we will be successful in implementing our new business strategy. In addition, moving to a new business strategy may result in a loss of established efficiency, which may have a negative impact on our business. We may also face an increased amount of competition as we attempt to expand and grow our business, which may negatively impact our results of operations, cash flows and financial condition.

Our Digital Asset holdings will be less liquid than existing cash and cash equivalents and may not be able to serve as a source of liquidity to the same extent as cash and cash equivalents.

Historically, the Digital Assets markets have been characterized by significant volatility in price, limited liquidity and trading volumes compared to sovereign currencies markets, relative anonymity, a developing regulatory landscape, potential susceptibility to market abuse and manipulation, compliance and internal control failures at exchanges, and various other risks inherent in its entirely electronic, virtual form and decentralized network. During times of market instability, we may not be able to sell our Digital Assets at favorable prices or at all. As a result, our Digital Asset holdings may not be able to serve as a source of liquidity for us to the same extent as cash and cash equivalents. Further, the Digital Assets we intend to hold with our custodians and transact with our trade execution partners does not enjoy the same protections as are available to cash or securities deposited with or transacted by institutions subject to regulation by the Federal Deposit Insurance Corporation or the Securities Investor Protection Corporation. Additionally, we may be unable to enter into term loans or other capital raising transactions collateralized by our unencumbered Digital Assets, or otherwise generate funds using our Digital Asset holdings, including in particular during times of market instability or when the price of a Digital Asset has declined significantly. If we are unable to sell any of our Digital Assets, enter into additional capital raising transactions using any of our Digital Assets as collateral, or otherwise generate funds using our Digital Assets holdings, or if we are forced to sell our Digital Assets at a significant loss, in order to meet our working capital requirements, our business and financial condition could be negatively impacted.

If we or our third-party service providers experience a security breach or cyberattack and unauthorized parties obtain access to our Digital Assets, we may lose some or all of our Digital Assets and our financial condition and results of operations could be materially adversely affected.

Our Digital Assets are or will be held in custody accounts. We could have a high concentration of Digital Assets in one location or with one custodian, which may be prone to losses arising out of hacking, loss of passwords, comprised access credentials, malware, or cyberattacks. Security breaches and cyberattacks are of particular concern with respect to our Digital Asset holdings. Digital Assets and the entities that provide services to participants in the Digital Asset ecosystem have been, and may in the future be, subject to security breaches, cyberattacks, or other malicious activities. A successful security breach or cyberattack could result in:

- a partial or total loss of our Digital Assets in a manner that may not be covered by insurance or the liability provisions of the custody agreements with the custodians who hold our Digital Assets;
- harm to our reputation and brand;
- improper disclosure of data and violations of applicable data privacy and other laws; or
- significant regulatory scrutiny, investigations, fines, penalties, and other legal, regulatory, contractual and financial exposure.

Further, any actual or perceived data security breach or cybersecurity attack directed at other companies with Digital Assets or companies that operate blockchain networks, regardless of whether we are directly impacted, could lead to a general loss of confidence in the broader blockchain ecosystem or in the use of the digital asset network to conduct financial transactions, which could negatively impact us.

Attacks upon systems across a variety of industries, including industries related to Digital Assets, are increasing in frequency, persistence, and sophistication, and, in many cases, are being conducted by sophisticated, well-funded and organized groups and individuals, including state actors. Any future breach of our operations or those of others in the digital asset industry, including third-party services on which we rely, could materially and adversely affect our financial condition and results of operations.

We face risks relating to the custody of our Digital Assets, including the loss or destruction of private keys required to access our Digital Assets, and cyberattacks or other data loss relating to our Digital Assets.

We hold our Digital Assets with regulated custodians that have duties to safeguard our private keys. Our custodial services contracts do not restrict our ability to reallocate our Digital Assets among our custodians, and our Digital Assets holdings may be concentrated with a single custodian from time to time. In light of the significant amount of Digital Assets we anticipate that we may hold, we continually seek to engage additional custodians to achieve a greater degree of diversification in the custody of our Digital Assets as the extent of potential risk of loss is dependent, in part, on the degree of diversification. If there is a decrease in the availability of Digital Asset custodians that we believe can safely custody our Digital Assets, for example, due to regulatory developments or enforcement actions that cause custodians to discontinue or limit their services in the United States, we may need to enter into agreements that are less favorable than our current agreements or take other measures to custody our Digital Assets, and our ability to seek a greater degree of diversification in the use of custodial services would be materially adversely affected. In addition, holding our Digital Assets with regulated custodians could affect the availability of receiving Digital Assets that may result from “forks” of the blockchain networks if our custodians are unable to support or otherwise provide us with such Digital Assets, thereby reducing the amount of Digital Assets we may hold as a result. While our custodians carry insurance policies to cover losses for commercial crimes, cyber and cold storage, the policy limits vary per provider and would be shared among all of their customers, and subject to various limitations and exclusions (such as if a loss arises due to our failure to protect our login credentials and devices). The insurance that covers losses of our Digital Asset holdings may cover only a small fraction of the value of the entirety of our Digital Asset holdings, and there can be no guarantee that such insurance will be maintained as part of the custodial services we have or that such coverage will cover losses with respect to our Digital Assets. Moreover, our use of custodians exposes us to the risk that the Digital Assets our custodians hold on our behalf could be subject to insolvency proceedings and we could be treated as a general unsecured creditor of the custodian, inhibiting our ability to exercise ownership rights with respect to such Digital Assets. Any loss associated with such insolvency proceedings is unlikely to be covered by any insurance coverage we maintain related to our Digital Assets.

Digital Assets are controllable only by the possessor of both the unique public key and private key(s) relating to the local or online digital wallet in which the assets are held. While the digital asset blockchain ledger requires a public key relating to a digital wallet to be published when used in a transaction, private keys must be safeguarded and kept private in order to prevent a third party from accessing the digital asset held in such wallet. To the extent the private key(s) for a digital wallet are lost, destroyed, or otherwise compromised and no backup of the private key(s) is accessible, neither we nor our custodians will be able to access the digital asset held in the related digital wallet. Furthermore, we cannot provide assurance that our digital wallets, nor the digital wallets of our custodians held on our behalf, will not be compromised as a result of a cyberattack. The digital asset and blockchain ledger, as well as other Digital Assets and blockchain technologies, have been, and may in the future be, subject to security breaches, cyberattacks, or other malicious activities.

Our custodially-held Digital Assets may become part of the custodian’s insolvency estate if one or more of our custodians enters bankruptcy, receivership or similar insolvency proceedings.

If our Digital Assets held by a custodian are considered to be the property of our custodians’ estates in the event that any such custodians were to enter bankruptcy, receivership or similar insolvency proceedings, we could be treated as a general unsecured creditor of such custodians, inhibiting our ability to exercise ownership rights with respect to such Digital Asset and this may ultimately result in the loss of the value related to some or all of such Digital Assets. A series of recent high-profile bankruptcies, closures, liquidations, regulatory enforcement actions and other events relating to companies operating in the Digital Asset industry, including the filings for bankruptcy protection by Three Arrows Capital, Celsius Network, Voyager Digital, FTX Trading and Genesis Global Capital, the closure or liquidation of certain financial institutions that provided lending and other services to the Digital Assets industry, including Signature Bank and Silvergate Bank, SEC enforcement actions against Coinbase, Inc. and Binance Holdings Ltd., the placement of Prime Trust, LLC into receivership following a cease-and-desist order issued by Nevada’s Department of Business and Industry, and the filing and subsequent settlement of a civil fraud lawsuit by the New York Attorney General against Genesis Global Capital, its parent company Digital Currency Group, Inc., and former partner Gemini Trust Company, have highlighted the counterparty risks applicable to owning and transacting in Digital Assets. Additional bankruptcies, closures, liquidations, regulatory enforcement actions or other events involving participants in the Digital Asset industry in the future may further negatively impact the adoption rate, price, and use of Digital Assets, limit the availability to us of financing collateralized by Digital Assets that we hold, or create or expose additional counterparty risks. Any loss associated with such insolvency proceedings is unlikely to be covered by any insurance coverage we maintain related to our Digital Assets. Even if we are able to prevent our Digital Assets from being considered the property of a custodian’s bankruptcy estate as part of an insolvency proceeding, it is possible that we would still be delayed or may otherwise experience difficulty in accessing our Digital Assets held by the affected custodian during the pendency of the insolvency proceedings. Any such outcome could have a material adverse effect on our financial condition and the market price of our common stock.

Digital Assets held by us are not subject to FDIC or SIPC protections.

We will not hold our Digital Assets with a banking institution or a member of the Federal Deposit Insurance Corporation (FDIC) or the Securities Investor Protection Corporation (SIPC), and, therefore, our Digital Assets are not subject to the protections enjoyed by depositors with FDIC or SIPC member institutions. As a result, we may suffer a loss with respect to our Digital Assets that is not covered by insurance, and we may not be able to recover any of our carried value in these Digital Assets if they are lost or stolen or suffer significant and sustained reduction in conversion spot price. If we are not otherwise able to recover damages from a malicious actor in connection with these losses, our business and results of operations may suffer, which may have a material negative impact on our stock price.

Digital Assets are novel assets, and are subject to significant legal, commercial, regulatory, and technical uncertainty.

Digital Assets are relatively novel and are subject to rapidly evolving legal, commercial, regulatory, and technical landscapes. Because the application of federal and state securities and other applicable laws, regulations, and rules (Applicable Law) remain unsettled in several material respects, there is substantial risk that a governmental or regulatory authority could adopt or interpret Applicable Law in a manner that adversely affects the price of Digital Assets. Increased regulatory scrutiny may result in additional costs for us and may require our management team to devote increased time and attention to regulatory matters, change aspects of our business, or result in limits on the utility of Digital Assets. Moreover, the regulatory landscape with respect to Digital Assets is rapidly changing and we may be required to comply with any new laws, regulations, or interpretations, which may result in heightened regulatory and compliance related costs, litigation, regulatory investigations, and enforcement or other actions. Adverse changes to, or our failure to comply with Applicable Law may have an adverse effect on our reputation, brand, our business, operating results, and financial condition. Further, if any of our Digital Assets are determined to constitute a security for purposes of U.S. federal securities laws, the additional regulatory restrictions imposed by such a determination could adversely affect the market price of the Digital Assets we hold.

The U.S. federal government, states, regulatory agencies, and foreign countries may also enact new laws and regulations, or pursue regulatory, legislative, enforcement or judicial actions, that could materially impact the price of Digital Assets or the ability of individuals or institutions such as us to own or transfer Digital Assets. Regulatory authorities have been evolving in their approach to Digital Assets. It is not possible to predict whether, or when, any of these developments will lead to U.S. Congress granting additional authorities to the SEC or other regulators, or whether any other federal, state, or foreign legislative bodies will take any similar actions. It is also not possible to predict the nature of any such additional authorities, how additional legislation or regulatory oversight might impact the ability of Digital Asset markets to function or the willingness of financial and other institutions to continue to provide services to the Digital Assets industry, nor how any new regulations or changes to existing regulations might impact the value of Digital Assets generally and any Digital Assets we hold specifically. The consequences of increased regulation of Digital Assets and Digital Asset-related activities could adversely affect the market price of any Digital Assets we hold and in turn adversely affect the market price of our common stock.

Moreover, the risks of engaging in a Digital Asset treasury strategy are relatively novel and have created, and could continue to create, complications due to the lack of experience that third parties have with companies engaging in such a strategy, such as increased costs of director and officer liability insurance or the potential inability to obtain such coverage on acceptable terms in the future.

The liquidity of Digital Assets may also be impacted to the extent that changes in Applicable Laws and regulatory requirements negatively impact the ability of exchanges and trading venues to provide services for Digital Assets. The evolving regulatory landscape creates uncertainty for the Company, as new regulations or changes to existing regulations could materially and adversely affect our business operations, financial condition, and results of operations. The effect of any future regulatory change on the Company is impossible to predict, but such change could be substantial and adverse.

We could be subject to legal or regulatory action, including fines, in the event the SEC, a foreign regulatory authority, or a court were to determine that a digital asset held by us is a “security” under applicable laws.

While all investments entail a risk of loss of capital, investments in Digital Assets should be considered substantially more speculative and significantly more likely to result in a loss, including a total loss of capital, than many other forms of investment. The investment characteristics of Digital Assets differ from those of many traditional currencies, commodities, and securities. A particular Digital Asset’s status as a “security” in any relevant jurisdiction is subject to a high degree of uncertainty, and if we are unable to properly characterize a Digital Asset, we may be subject to regulatory scrutiny, investigations, fines, and other penalties, which may adversely affect our business, results of operations and/or financial condition.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain effective patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets

We rely upon a combination of patents, trade secret protection, trademarks, and confidentiality agreements to protect the intellectual property related to our product candidates and development programs. Our success depends in large part on our ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries with respect to various proprietary elements of our product candidates, such as, for example, our product formulations and processes for manufacturing our products and our ability to maintain and control the confidentiality of our trade secrets and confidential information critical to our business.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. There is no guarantee that any patent application we file will result in an issued patent having claims that protect our products; and, as a result, we may not be able to effectively prevent others from commercializing competitive products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar patent protection covering our products in all jurisdictions where we file patent applications. If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any product candidate, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize any product candidates that are approved. Any such outcome could have a materially adverse effect on our business.

The patents and patent applications that we own or in-license may fail to result in issued patents with claims that protect our present and future product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover our present or future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any present or future product candidates or methods of using such. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The patent position of biopharmaceutical companies is generally uncertain and involve complex legal and factual questions and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability and commercial value of our patent rights are uncertain. The pending patent applications that we own or license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries for many reasons. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, considered or cited during patent prosecution, which can be used to invalidate a patent or prevent a patent from issuing from a pending patent application.

Moreover, we may in the future be subject to a third-party pre-issuance submission of prior art to the USPTO. We may also become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. For example, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate 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. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. The scope of patent protection may also be limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such 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 owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Method of use patents protect the use of a product for the specified method or indication. In the absence of separate composition of matter protection, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidate(s) for an indication that is outside of the methods of use claimed in our patents. Moreover, even if competitor products are not approved for use in our patented indications, and our competitors do not actively promote their products for indications that are covered by our patents, clinicians may prescribe these competitor products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, such infringement is difficult to prevent or prosecute.

We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that patent searches, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

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 our products or pipeline candidates. We may incorrectly determine that our products are not covered by a third-party patent. Further, we may conclude that a well-informed court or other tribunal would find the claims of a relevant third-party patent to be invalid based on prior art, enablement, written description, or other ground, and that conclusion may be incorrect, which may negatively impact our ability to market our products or pipeline molecules.

Many patents may cover a marketed product, including the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of a reference product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. We may not identify all relevant patents, or incorrectly determine their expiration dates, which may negatively impact our ability to develop and market our products.

Failure to identify and correctly interpret relevant patents may negatively impact our ability to develop, market and commercialize our products.

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

The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in future and whether patent expiration dates may be impacted.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, all European patents, including those issued prior to June 1, 2023, now by default automatically fall under the jurisdiction of a new European Unified Patent Court (the UPC) for litigation involving such patents. As the UPC is a relatively new court system, there is uncertainty regarding litigation at the UPC. 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 our future 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, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain a pan-European injunction. It is uncertain how the UPC will impact granted European patents in the pharmaceutical industry.

Additionally, recent reforms and changes at government agencies of the United States and those of non-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications, and the maintenance, enforcement, or defense of our issued patents. For example, the ability of the USPTO and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency and their ability to retain key personnel and fill key leadership appointments, among various factors. Termination of employees or delays in replacing or hiring for key positions could significantly impact the ability of the USPTO and other applicable patent authorities to fulfill their functions and could greatly impact our ability to timely and adequately prosecute or maintain our patent applications, and our ability to timely and adequately maintain, enforce, or defend our issued patents.

Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or prevent our development and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, reexamination, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization.

There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. The existence of any patent with valid and enforceable claims covering one or more of our product candidates could cause substantial delays in our ability to introduce a candidate into the U.S. market if the term of such patent extends beyond our desired product launch date.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions that do not require publication of patent applications until 18 months after filing.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon these rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms.

Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, product candidate(s), or the use of our product candidate(s). 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 may be infringed by the manufacture, use, or sale of our technologies or product candidate(s) or will prevent, limit, or otherwise interfere with our ability to make, use, or sell our technologies and product candidate(s).

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms.

In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our products. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights.

Third parties may submit applications for patent term extensions in the United States or other jurisdictions where similar extensions are available and/or Supplementary Protection Certificates in the EU states seeking to extend certain patent protection that, if approved, may interfere with or delay the launch of one or more of our product candidates.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

Furthermore, as the patent landscape is crowded and highly competitive, even in the absence of litigation we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. 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 face commercial competition, which could harm our business. We cannot provide any assurances that third-party patents do not exist which might be enforced against product candidates resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development or manufacture of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates. In each of these cases, we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, 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 larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We may develop or license intellectual property for which development was funded or otherwise assisted by, the U.S. government and/or government agencies, such as the National Institutes of Health, for development of our technology and product candidates. Failure to meet our own obligations to future licensors or upstream licensors, including such government agencies, may result in the loss of our rights to such intellectual property, which could harm our business.

The U.S. government and/or government agencies may provide funding, facilities, personnel, or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. The U.S. government and/or government agencies may retain rights in such intellectual property, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses, could result in the loss of significant rights and could harm our ability to commercialize licensed products. For example, research resulting in future in licensed patent rights and technology that was funded in part by the U.S. government could result in the government having certain rights, or march in rights, to such patent rights and technology which may permit the government to disclose our confidential information to third parties and to exercise march in rights to use or allow third parties to use our licensed technology, potentially on unfavorable terms or without adequate compensation.

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid and/or unenforceable. 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, written description, or lack of patentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant material information from the USPTO or made a materially misleading statement during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. Because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States 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. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and there is a risk that a court will decide that a patent of ours 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 and 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 that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). 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 business position, business prospects and financial condition. 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.

We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

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.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the market price of common shares. Moreover, there can be no assurance that we will 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.

We may be subject to claims challenging ownership of intellectual property rights and that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals and retain independent contractors and consultants, or in the future, may employ individuals and retain independent contractors and consultants, who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, independent contractors, consultants, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that such persons or other third parties have an ownership interest in our intellectual property.. We may also be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of such persons' former companies or other third parties.. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. 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 we require our employees, consultants and contractors who may be involved in the 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 develops intellectual property that we regard as our own, which may result in claims by or against us asserting ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights with respect to certain clinical programs.

We are party to certain license agreements with respect to certain of our product candidates outside of our VT7208 clinical program pursuant to which we were granted rights to intellectual property in connection with the development, manufacture and commercialization of such product candidates. If we fail to comply with our obligations under these agreements or if we are subject to a bankruptcy, we may be required to make certain payments to the licensor of our license or the licensor may have the right to terminate the license, and in the event of termination we may not be able to develop or market products covered by the license. In the event we breach any of our obligations under these agreements, we may incur significant liability to our licensing partners. Disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patents and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and that could harm our business.

In addition, our license agreements do, and we expect that future license agreements will, impose various diligence, milestone payment, royalty, insurance and/or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor(s) may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology, and could compromise our development and commercialization efforts for our product candidates.

We have continuing obligations to make certain operational and financial milestone payments under our license for VT7208.

We obtained our BTK inhibitor program, including certain compounds and related program assets through an acquisition of a subsidiary of Gossamer Bio, Inc. (Gossamer). There are certain license fees and milestone payments required to be paid by us to Gossamer pursuant to the terms of our agreement with Gossamer (Gossamer Agreement). The Gossamer Agreement requires us to pay one-time development and regulatory milestone payments upon achievement of specified milestone events, up to an aggregate of \$165.5 million, tiered net sales-based earn-out payments on sales of products derived from the Gossamer Compounds at rates ranging from low- to mid-single digit percentages depending on certain annual net sales thresholds and up to 5% of the consideration in a qualifying transaction involving a change of control of the Company, sale of the compounds or substantially all of the program assets, subject to certain exceptions. These development and milestone payment obligations could increase our need for additional capital to continue developing VT7208, the net royalty obligations will reduce any future revenue anticipated from commercialization of VT7208, if approved, and payments due on any subsequent qualifying transaction may make the Company less attractive to a potential acquiror, all of which could adversely affect our business and financial condition.

We are evaluating strategic opportunities for certain legacy pharmaceutical assets, and any outcome of that evaluation could result in additional costs, delays or dilution.

In addition to VT7208, we continue to hold certain legacy product candidates outside of our VT7208 clinical program. We are evaluating a range of strategic opportunities designed to maximize the clinical and long-term value of these legacy assets, which could include continued internal development, out-licensing, partnering, sale, or the contribution of some or all of these assets to a newly formed or spun-out entity. We have not made a final decision as to the path we will pursue for any of these legacy assets, and there is no assurance that we will identify or complete any strategic transaction on favorable terms or at all. Any such transaction, or the failure to complete one, could require us to incur additional costs, including transaction costs, could divert management attention from VT7208, and, if it involves the issuance of equity or equity-linked securities, could dilute our stockholders. In addition, if we determine to discontinue development of any of these legacy assets, we could incur wind-down costs and remain subject to surviving contractual obligations, such as confidentiality, indemnification or reversion rights in favor of the applicable licensor.

We may be subject to claims challenging the inventorship of our patent filings and other intellectual property.

We may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use valuable intellectual property. Such an outcome could harm 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.

Any trademarks we may obtain for our product candidates may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our product candidates or any other product candidate 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. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA 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 proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Moreover, the information embodied in our trade secrets and confidential information may be independently and legitimately developed or discovered by third parties without any improper use of or reference to information or trade secrets. We seek to protect the scientific, technical and business information supporting our operations, as well as the confidential information relating specifically to our product candidates by entering into confidentiality agreements with parties to whom we need to disclose our confidential information, such as, our employees, consultants, board members, contractors, potential collaborators and financial investors. However, we cannot be certain that such agreements have been entered into with all relevant parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. Our confidential information and trade secrets thus may become known by our competitors in ways we cannot prove or remedy.

Although we require all of our employees and consultants to assign their inventions to us, and 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, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may harm our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the “first-to-file” laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting, defending and enforcing patents and trademarks on product candidates in all countries throughout the world would be prohibitively expensive, and our 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. Further, licensing partners may choose not to file patent or trademark applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions and we may not be able to use our trademarks in all countries or prevent others from using or registering similar trademarks. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, 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 generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not being approved, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Governments of some foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. In addition, many countries limit the enforceability of patents against government agencies or government contractors. 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 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 technologies and product candidate(s). While we will endeavor to try to protect our technologies and product candidate(s) 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 other 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. As a result, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. We rely on our outside counsel or third-party vendors to pay these fees. The USPTO, Canadian Intellectual Property Office (CIPO) and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While, 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 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. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our present and future product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

Risks Related to our Business Operations

We will be required to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As our development and commercialization plans and strategies develop, and as we continue operating as a public company, we expect to need and to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, if our product candidate receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial and human resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel, as the competition for individuals in autoimmune disease product development is high. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and the expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our future success depends on our ability to retain key members of senior management and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biopharmaceutical industry depends upon our ability to attract and retain highly qualified management, research and development, clinical, financial and business development personnel. Our senior management may terminate their employment with us at any time, and we do not maintain “key person” insurance for any of our employees.

As of September 15, 2026, we had 9 full-time employees. Our employees are not represented by labor unions or covered by collective bargaining agreements. We believe that our employee morale is healthy and consider our relationship with our employees to be good.

The Merger resulted in a combined employee and consultant base that is small relative to our development ambitions. We are heavily dependent on a limited number of individuals with specialized expertise in autoimmune diseases and BTK inhibitor development. In addition, many individuals who historically provided services to Vidya Therapeutics, Inc. (Vidya) were, and following the Merger continue to serve the Company as, consultants serving on a part-time basis. The loss of one or more of these individuals, particularly during the critical post-Merger integration period, could significantly delay our clinical development programs. Competition for individuals with this specialized expertise is intense, and we may not be able to recruit suitable replacements on acceptable terms or in a timely manner.

Recruiting and retaining qualified scientific and clinical personnel, in light of the recent merger and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of members of our senior management or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing members of our senior management and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers, as well as junior, mid-level and senior scientific and medical personnel. Competition to hire from this limited candidate pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Additionally, most of our employees work remotely and because of the challenges of working remotely, their full productivity requires different approaches to onboarding and managing. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

We are subject to costs and risks relating to compliance with a variety of federal, state, and local laws pertaining to labor and employment, including employee health and safety, equal employment opportunity, and wage and hour compliance. We may, from time to time, be subject to litigation or administrative actions resulting from claims against us by current or former employees individually or as part of class actions, including claims of wrongful terminations, discrimination, misclassification or other violations of labor law or other alleged conduct. Ensuring the health, safety and well-being of our employees is essential to our operations. We may incur increased costs or disruptions in connection with implementing and maintaining workplace health and safety measures, complying with evolving regulations and guidance, and addressing public health concerns. Any failure to maintain safe and compliant working environments across our facilities and for our distributed workforce could adversely affect our ability to attract and retain personnel and could expose us to liability. We may also, from time to time, be subject to litigation resulting from claims against us by third parties, including claims of breach of non-compete and confidentiality provisions of our employees’ former employment agreements with such third parties. Our failure to comply with applicable regulatory requirements could have a material adverse effect on our revenue, business, results of operations and financial condition.

Following the Merger, certain of our consultants who previously worked at a private company are now subject to public company compliance obligations, and any failure to comply with these obligations could expose us to regulatory risk and reputational harm.

As a result of the Merger, a number of individuals who previously operated in a private company environment are now consultants of a publicly traded company and are subject to public company compliance obligations, including compliance with our insider trading policy, Section 16 reporting requirements under the Securities Exchange Act of 1934, Regulation FD restrictions on selective disclosure of material nonpublic information, and quiet period restrictions around SEC filings. These individuals may not have prior experience with public company compliance requirements.

We have implemented onboarding and training programs to educate former Vidya consultants regarding these obligations. However, there can be no assurance that all individuals will fully understand or consistently comply with these requirements, particularly during the initial post-Merger integration period. Any inadvertent violation of insider trading laws, Section 16 reporting obligations, or Regulation FD could result in SEC enforcement action, personal liability for the individuals involved, and reputational harm to the Company. Such violations could also undermine investor confidence in our corporate governance practices and adversely affect the trading price of our common stock.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses, as we may deem appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Additionally, if we undertake future acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expenses. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently maintain product liability insurance with coverage in the aggregate and a per incident limit at an amount that we believe is adequate to cover estimated liabilities that we may incur. We may need to increase our insurance coverage if we re-initiate our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to our Securities and our Status as a Public Company

The trading price of our common stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the common stock. In addition to the factors discussed elsewhere in this “Risk Factors” section, these factors include:

- the commencement, enrollment or results of our clinical trials;
- positive or negative results from, or delays in, testing and clinical trials by us, collaborators or competitors;
- the loss of any of our key scientific or management personnel;
- regulatory or legal developments in the United States and other countries;
- the success of competitive products or technologies;

- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;
- changes or developments in laws or regulations applicable to our product candidates and preclinical program;
- changes in the structure and scope of health care payment systems;
- changes to our relationships with collaborators, manufacturers or suppliers;
- concerns regarding the safety of our product candidates ;
- announcements concerning our competitors or the pharmaceutical industry in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions, financing, collaborations or other corporate transactions;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- the trading volume of our common stock on Nasdaq;
- sales of our common stock by us, members of our senior management and directors or our stockholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- investors' general perception of us and our business; and
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their common stock at or above the price paid for the common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. From time to time, we have been, and may continue to be, subject to legal proceedings and claims in the ordinary course of business. We also may decide to settle lawsuits on unfavorable terms.

Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

Our business and operations could be negatively affected by any securities litigation or stockholder activism, which could cause us to incur significant expense, hinder execution of business and growth strategies and impact our share price.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Stockholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. Volatility in the stock price of our common stock or other securities or other reasons may in the future cause us to become the target of securities litigation or stockholder activism.

Securities litigation and stockholder activism, including proxy contests, could result in substantial costs and divert management's and the Board's attention and resources from our business. The potential of a proxy contest or other stockholder activism could interfere with our ability to execute on our strategic plan, give rise to perceived uncertainties as to our future direction, result in the loss of potential business opportunities or make it more difficult to attract and retain qualified personnel, any of which could materially and adversely affect our business and operating results. Further, our share price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any securities litigation and stockholder activism.

Litigation or legal proceedings could expose us to significant liabilities and have a negative impact on our business.

From time to time, we may be party to various claims and litigation proceedings. We evaluate these claims and litigation proceedings to assess the likelihood of unfavorable outcomes and to estimate, if possible, the amount of potential losses. Based on these assessments and estimates, we may establish reserves, as appropriate. These assessments and estimates are based on the information available to management at the time and involve a significant amount of management judgment. Actual outcomes or losses may differ materially from its assessments and estimates.

On May 10, 2024, we filed a lawsuit against Elion Oncology, Inc. (Elion) disputing the purported termination of our license agreement, dated August 23, 2020 (the Elion License Agreement), with Elion, which lawsuit is subject to counterclaims by Elion. On July 23, 2026, we terminated the Elion License Agreement, by entering into a settlement agreement (the Settlement Agreement) with Elion. Pursuant to the Settlement Agreement, we and Elion agreed to settle all claims in respect of the lawsuit and to terminate the Elion License Agreement without further obligation of either party, with us returning our PCS6422 program to Elion. In connection with the Settlement, we and Elion exchanged mutual releases of all claims relating to the Elion License Agreement, the PCS6422 program and the related litigation. As part of the settlement, we paid Elion the sum of \$650,000 towards Elion's attorneys' fees and/or other out-of-pocket costs. In addition, we agreed to grant to Elion a non-voting equity interest equal to 7.5% of the fully diluted pre-money equity capitalization of any newly formed entity (NewCo) whose assets include one or more of PCS499, PCS11-T and/or PCS12852, if the formation or spin-out of NewCo is completed within 365 days following the effective date of the Settlement Agreement.

In addition, on December 3, 2024, two of the investors in our February 2021 private offering filed a lawsuit alleging fraud and negligent misrepresentation in connection therewith and seeking monetary damages. The court dismissed two of the three counts of the complaint (for constructive fraud and negligent misrepresentation) and dismissed that part of the remaining cause of action for fraud to the extent that it related to the retention of Plaintiffs' investment (leaving only the portion of the claim in which Plaintiffs allege they were fraudulently induced to invest in the Company in February 2021). In January 2026, Plaintiffs were granted leave to amend their complaint to add a claim for breach of contract against us and David Young. Our and David Young's response to the amended complaint (a motion to dismiss) was submitted on March 2, 2026 and is still pending before the Court. At the Court's request, we also filed a non-substantive submission concerning oral argument. We expect to draft and file a motion for summary judgment in the fourth quarter. We intend to vigorously defend ourselves in this lawsuit and cannot at this time predict the likely outcome of such litigation, reasonably determine either the probability of a material adverse result or any estimated range of potential exposure, or reasonably determine how this matter or any future matters might impact our business, our financial condition, or our results of operations, although such impact, including the costs of defense, as well as any judgments or indemnification obligations, among other things, could be materially adverse to us.

Lawsuits have diverted and may in the future divert our management's attention, and we may incur significant expenses in defending any lawsuits. The results of litigation and other legal proceedings are inherently uncertain, and adverse judgments or settlements in any legal dispute may result in monetary damages, penalties or injunctive relief, or the termination of license agreements, which could have a material adverse effect on our financial position, cash flows or results of operations. While we maintain insurance for certain potential liabilities, such insurance does not cover all types of potential liabilities and is subject to various exclusions, as well as limits on amounts recoverable.

A significant portion of our total outstanding shares may be sold into the market, which could cause the market price of our common stock to drop 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. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our shares of common stock in the public market, the market price of our common stock could decline significantly.

In addition, we have filed registration statements registering the issuance of all shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements will be available for sale in the public market following vesting, exercise and/or settlement (as applicable) of the equity awards and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

Furthermore, certain holders of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Finally, in connection with the execution of the Agreement and Plan of Merger (the Merger Agreement), dated as of July 28, 2026, by and among the Company, Vidya, Venus Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, Venus Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company, certain of our directors and officers, as well as certain of the directors, officers and stockholders of Vidya, each as of immediately prior to the Merger, entered into lock-up agreements for a period of 180 days following the closing of the Merger, pursuant to which each such stockholder is subject to restrictions on the sale or transfer of shares of our common stock and Series A Preferred Stock held by each such stockholder at the closing, including, in the case of specified officers, directors and stockholders of Vidya, those shares received by them in the Merger, subject to certain limited exceptions as set forth in such lock-up agreements. Upon expiration of this lockup period, these shares will become eligible for sale in the public market. Pursuant to the Merger Agreement and the registration rights agreement that we entered into pursuant to the 2026 Private Placement, we are obligated to prepare and file a resale registration statement with the SEC to register the resale of shares of our common stock underlying the Series A Preferred Stock. We will use reasonable best efforts to cause this registration statement to be declared effective by the SEC. Once the registration statement is declared effective, the shares subject to the registration statement will no longer constitute restricted securities and may be sold freely in the public markets, subject to (i) the approval of the Required Company Stockholder Matters (as defined below), (ii) the approval of the Nasdaq Listing Application (as defined below) and (iii) any beneficial ownership limitations set by the holder of Series A Preferred Stock. Certain additional holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in Securities Act registration statements that we may file for ourselves or other stockholders. If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future.

We do not intend to pay any cash dividends on our common stock in the foreseeable future and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. Therefore, you should not rely on an investment in our common stock to provide dividend income. Our board of directors has complete discretion as to whether to distribute dividends. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. As a result, capital appreciation, if any, on our common stock will be your sole source of gains for the foreseeable future.

Changes in tax law could adversely affect our business and financial condition.

We are subject to federal, state and local income and other taxes in the United States and in foreign jurisdictions because of the scope of our operations. New tax laws, statutes, rules, regulations or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted differently, changed, repealed or modified at any time. Any such enactment, interpretation, change, repeal or modification could adversely affect us, possibly with retroactive effect. For example, the U.S. government recently enacted legislation commonly referred to as the One Big Beautiful Bill Act that (along with prior U.S. federal tax reform legislation) has resulted in significant changes to the taxation of business entities, including, among other changes, the imposition of minimum taxes and excise taxes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other taxing authorities with respect to this and other legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years. In addition, it is uncertain if and to what extent various states will conform to federal law. We continue to evaluate the impact that these and other tax reforms may have on our business. To the extent that any such changes in tax laws and regulations have a negative impact on us, including as a result of related uncertainty, our business, financial condition, results of operations and cash flows may be materially and adversely impacted and we may be required to implement changes to minimize increases in our tax liability.

Our ability to use our NOLs to offset future taxable income may be subject to certain limitations.

Our net operating loss (NOL), carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. U.S. federal NOLs generated in taxable years beginning before January 1, 2018 are permitted to be carried forward for only 20 taxable years under applicable U.S. federal income tax law. Under the Tax Cuts and Jobs Act of 2017 (the Tax Act), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), NOLs arising in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs generally will be limited in taxable years beginning after December 31, 2020 to 80% of current year taxable income. As of December 31, 2025, we had federal and state net operating loss carryforwards of approximately \$54.8 million, of which \$54.5 million will not expire and the remainder begin expiring in 2037. Additionally, as of December 31, 2025, we had federal and state research and development tax credits of approximately \$1.2 million, prior to consideration of annual limitations that may be imposed under Section 382 of the Code. The federal research and development tax credits have a 20-year carryforward period.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” (as defined under Section 382 of the Code and applicable Treasury Regulations) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. Following the approval of the Required Company Stockholder Matters, the Merger will result in an ownership change for us and, accordingly, our NOL carryforwards and certain other tax attributes will be subject to limitations (or disallowance) on their use after approval of the Required Company Stockholder Matters. Vidya's NOL carryforwards may also be subject to limitations as a result of prior shifts in equity ownership and/or the Merger. We may also have experienced an ownership change in the past, and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. Furthermore, our ability to utilize NOLs of Vidya we have acquired as a result of the Merger may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For these reasons, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our operating results and financial condition.

We have incurred and expect to continue incurring significantly increased costs as a result of operating as a company whose common stock is publicly traded, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred significant legal, accounting and other expenses that we did not incur previously, as a private company. These expenses will likely be even more significant after we no longer qualify as an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, 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.

Pursuant to Section 404, we are required to furnish a report by our senior management on our internal control over financial reporting. Depending upon our filer status, we could also be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm as required by Section 404(b). To prepare for eventual compliance with Section 404, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404.

Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock.

Our amended and restated certificate of incorporation, as amended, and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions. These provisions include:

- providing for a classified board of directors with staggered, three-year terms;
- authorizing our board of directors to issue preferred stock with voting or other rights or preferences that could discourage a takeover attempt or delay changes in control;

- prohibiting cumulative voting in the election of directors;
- providing that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- prohibiting the adoption, amendment or repeal of our amended and restated bylaws or the repeal of the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors without the required approval of at least 66.67% of the shares entitled to vote at an election of directors;
- prohibiting stockholder action by written consent;
- limiting the persons who may call special meetings of stockholders; and
- requiring advance notification of stockholder nominations and proposals.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, the provisions of Section 203 of the Delaware General Corporate Law (the DGCL) govern us. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time without the consent of our board of directors.

These and other provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and under Delaware law could discourage potential takeover attempts, reduce the price investors might be willing to pay in the future for shares of our common stock and result in the market price of our common stock being lower than it would be without these provisions.

Our amended and restated certificate of incorporation, as amended, provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' abilities to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our directors, officers, employees or agents or our stockholders;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation also provides that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees. While the Delaware Supreme Court recently determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring such a claim arising under the Securities Act against us, our directors, officers, or other employees in a venue other than in the federal district courts of the United States of America. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation, and this may require significant additional costs associated with resolving such action in other jurisdictions.

Risks Related to the Merger

Pursuant to the terms of the Merger, we are required to recommend that our stockholders approve certain matters, including the conversion of all outstanding shares of our Series A Preferred Stock into shares of our common stock. We cannot guarantee that our stockholders will approve these matters, and if they fail to do so we may be required to settle such shares in cash and our operations may be materially harmed.

Under the terms of the Merger Agreement and the 2026 Private Placement purchase agreement, as promptly as practicable following the date of the Merger Agreement and pursuant to the Nasdaq Stock Market Rules, we are required to call and hold a meeting of our stockholders to obtain the requisite approval from our legacy stockholders for, among other things, (i) the issuance of shares of our common stock upon conversion of Series A Preferred Stock and exercise of certain options held by the former equity holders of Vidya that we assumed in the Merger, which (a) will represent more than 20% of the shares of our common stock outstanding pursuant to Nasdaq Listing Rule 5635(a) and (b) may, together with certain changes to management and our Board of Directors (Board), result in a change of control of the Company pursuant to Nasdaq Listing Rule 5635(b) (the Conversion Proposal), (ii) issuance of shares of our common stock, upon conversion of the shares of Series A Preferred Stock issued in the 2026 Private Placement, pursuant to Nasdaq Listing Rule 5635(d) (the Minimum Price Proposal), (iii) our 2027 Equity Incentive Plan (the EIP Proposal) and (iv) our 2027 Employee Stock Purchase Plan (the ESPP Proposal and, together with the Conversion Proposal, the Minimum Price Proposal and the EIP Proposal, the Required Company Stockholder Matters). If we fail to receive sufficient proxies to constitute a quorum or to obtain the required vote on the Required Company Stockholder Matters or we are otherwise required by Nasdaq Listing Rules, we would be required to adjourn or postpone the meeting one or more times for up to 30 days per adjournment or postponement. If stockholder approval of the Required Company Stockholder Matters is still not obtained following such adjournment(s) or postponement(s), we will be obligated to continue soliciting stockholder approval at subsequent annual or special meetings of our stockholders, held at intervals of at least every six months, until such approvals are obtained, which would be time consuming and costly.

There can be no assurance that our legacy stockholders will approve the Required Company Stockholder Matters. If our legacy stockholders do not approve the Conversion Proposal, we would be unable to issue the additional shares of our common stock necessary to complete the conversion of Series A Preferred Stock into our common stock, and may be unable to satisfy our other capital needs, which could have a material adverse effect on our business, financial condition, and prospects.

There can be no assurance that our legacy stockholders will approve the Required Company Stockholder Matters. Additionally, if the Conversion Proposal is not approved by the date that is nine months following the initial issuance date of the Series A Preferred Stock, the holders of the Series A Preferred Stock would be entitled to require us to settle their shares of our common stock underlying the Series A Preferred Stock for cash at a price per share equal to the fair value of our common stock at such time as described in the Certificate of Designation, provided that the Company has funds legally available for such payment. If we are forced to cash settle a significant amount of the shares of our common stock underlying the Series A Preferred Stock, it could materially affect our results of operations, business and financial condition.

Failure to obtain approval of the Nasdaq Listing Application, if required, could materially affect our results of operations, business and financial condition.

Pursuant to the Merger Agreement, we are required to use our reasonable best efforts to file the Nasdaq Listing Application to the extent required by the Nasdaq Listing Rules and to cause such Nasdaq Listing Application to be conditionally approved prior to the date of our stockholder meeting to approve the Required Company Stockholder Matters. Approval of a Nasdaq Listing Application may be required if Nasdaq determines there is a “change of control” under Nasdaq Listing Rule 5110(a). If we fail to meet the Nasdaq initial listing requirements and Nasdaq does not approve the Nasdaq Listing Application if and when required, we may be required to adjourn or postpone our stockholder meeting to approve the Required Company Stockholder Matters one or more times for up to 30 days per adjournment, continue to use our reasonable best efforts to obtain approval of the Nasdaq Listing Application and to continue soliciting stockholder approval of the Required Company Stockholder Matters at subsequent annual or special meetings of our stockholders, held at intervals of at least every six months, until such approval and the approval of the Required Company Stockholder Matters are obtained, which would be time consuming and costly. Additionally, if the Conversion Proposal is not approved by the date that is nine months following the initial issuance date of the Series A Preferred Stock, the holders of the Series A Preferred Stock would be entitled to require us to settle their shares of Series A Preferred Stock for cash at a price per share equal to the fair value of the Series A Preferred Stock at such time as described in the Certificate of Designation, provided that the Company has funds legally available for such payment. If we are forced to cash settle a significant amount of the shares of our common stock underlying the Series A Preferred Stock, it could materially affect our results of operations, business and financial condition. We cannot assure you that we will be able to meet Nasdaq’s initial listing standards if required. Furthermore, if we fail to obtain approval of the Nasdaq Listing Application to the extent required, we may be unable to execute on our plans for the Company following the Merger, which could materially affect our results of operations, business and financial condition.

There is no guarantee that the Merger will increase stockholder value.

In July 2026, we consummated the Merger, pursuant to which we acquired Vidya, and we closed the 2026 Private Placement. We cannot guarantee that implementing the Merger and related transactions will not impair stockholder value or otherwise adversely affect our business. The Merger poses significant integration challenges between our businesses and employees which could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of the Merger to our stockholders.

The failure to successfully integrate the businesses of the Company and Vidya in the expected timeframe could adversely affect our results of operations, financial condition, and future results.

Our ability to successfully integrate the operations of the Company and Vidya will depend, in part, on our ability to realize the anticipated benefits from the Merger. If we are not able to achieve these objectives within the anticipated time frame, or at all, the anticipated benefits of the Merger may not be realized fully, or at all, or may take longer to realize than expected, and the value of our common stock may be adversely affected. In addition, the integration of the Company’s and Vidya’s respective businesses will be a time-consuming and expensive process. Proper planning and effective and timely implementation will be critical to avoid any significant disruption to our operations. There can be no assurance that we will effectively manage the increased complexity of our business without experiencing operating inefficiencies or control deficiencies. Delays encountered in the integration process could have a material adverse effect on our expenses, operating results and financial condition, including the value of shares of our common stock.

We expect to incur substantial expenses related to the integration of Vidya.

We have incurred, and expect to continue to incur, substantial expenses in connection with the Merger and the integration of Vidya. There are a large number of processes, policies, procedures, operations, technologies and systems that must be integrated, including accounting and finance, billing, payroll, and benefits. Both the Company and Vidya have incurred significant transaction expenses in connection with the drafting and negotiation of the Merger Agreement, and the related ancillary agreements. While we have assumed that a certain level of expenses will be incurred, there are many factors beyond our control that could affect the total amount or the timing of the integration expenses. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. These integration expenses likely will result in our taking significant charges against earnings following the completion of the Merger, and the amount and timing of such charges are uncertain at present.

General Risk Factors

Our business, operations and clinical development plans and timelines, as well as the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, CROs, shippers, equipment suppliers and others, could be adversely affected by the effects of health epidemics.

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of third-party manufacturers, CROs and other third parties upon whom we rely. The effects of government orders may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays may occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not harm our business.

In addition, our preclinical studies and clinical trials may be affected by health epidemics. Clinical site initiation, patient enrollment and activities that require visits to clinical sites, including data monitoring, may be delayed due to prioritization of hospital resources toward the pandemic or concerns among patients about participating in clinical trials during a pandemic. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. These challenges may also increase the costs of completing our clinical trials. Similarly, if we are unable to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure or experience additional restrictions by their institutions, city or state, our clinical trial operations could be adversely impacted.

If our information systems or data, or those of our collaborators, contractors, consultants or other third parties with whom we work, are or were compromised, we could experience adverse consequences, including but not limited to regulatory investigations or actions; litigation; fines and penalties; significant disruption of our product development programs and our ability to operate our business effectively; reputational harm; and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work, process, collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share,, (collectively, process), proprietary, confidential, and sensitive data, including personal data, intellectual property, trade secrets and clinical trial data, (collectively, sensitive information).

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, security, integrity, and availability of our sensitive information 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, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some threat actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to conduct our clinical trials and other business .

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to computer viruses, malicious or unintentional actions or inactions that cause vulnerabilities, malware, software or hardware failure, supply chain attacks, social engineering (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing), credential stuffing, ransomware, unauthorized access, attacks enhanced or facilitated by artificial intelligence, (“AI”), natural disasters, terrorism, war and telecommunication and electrical failures. In particular, ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe, and can lead to significant interruptions in our operations, loss of 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.

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. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Future and past business transactions (such as acquisitions or mergers) 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 introduce cybersecurity risks and vulnerabilities, and other threats to our business operations. For example, we rely on third parties to operate critical business systems and process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, personnel email, and other functions. We also rely on third parties, including CROs, clinical trial sites and clinical trial vendors, to collect, store, and transmit sensitive data as part of our research activities. Our ability to monitor these third parties is limited, and these third parties may not have adequate information security measures. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover damages, or we may be unable to recover such awards. Supply-chain attacks have also 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.

Remote work has also increased risks to our information systems and data, as personnel utilize network connections, computers and devices outside of our premises or network.

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 (such as our hardware and/or software, including that of third parties with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities, including on a timely basis. Further, we have and may in the future experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats have in the past and may in the future cause a security incident or other interruption that have in the past and may in the future result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past, and expect such attempts will continue in the future. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to operate our business.

We have in the past and may in the future expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents, including where required by applicable data privacy and security laws or regulations or industry standards. Certain data privacy and security obligations require us to implement and maintain certain security measures.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, this could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information, significant delays or setbacks in our research, or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Such an actual or perceived security incident could also cause us to experience other adverse consequences, such as: loss of, or damage to, our data or applications, inappropriate disclosure of confidential or proprietary information, legal liability, exposure to litigation (including class claims) and regulatory enforcement action (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and/or oversight, fines, penalties, indemnification obligations, harm to our competitive position, reputational damage, and delay in the further development and commercialization of our product candidates.

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. Additionally, we cannot be certain that our insurance coverage will be adequate for data security liabilities actually incurred, will continue to be available to us on economically and commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim.

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 reveal competitively sensitive details about the company and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of ours could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative, agentic and other artificial intelligence (AI) technologies.

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

In the ordinary course of business, we process personal data and other sensitive information. 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.

In the United States, federal, state and local governments have enacted numerous privacy and data security laws, including federal and state health information privacy laws, federal and state security breach notification laws, federal and state consumer protection laws, and other similar laws (e.g., wiretapping laws). For example, at the federal level, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, many 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. 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 (CCPA) applies to personal data of consumers, business representatives, and employees who are California residents and requires businesses subject to the CCPA to provide specific disclosures in privacy notices and respond to requests of such individuals to exercise certain rights concerning their personal data. The CCPA provides fines for noncompliance and a limited private right of action in connection with certain data breaches. While the CCPA and other U.S. state comprehensive consumer privacy laws exempt certain personal data processed in connection with clinical trials, these developments could further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work. Similar laws have been passed or are being considered in several other states, as well as at the federal and local levels, and we expect more governments to pass similar laws in the future. The evolving patchwork of local, state and federal privacy and data security laws increases the cost and complexity of operating our business and increases our exposure to liability, including from third party litigation and regulatory investigations, enforcement, fines, and penalties.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR) the United Kingdom's General Data Protection Regulation (UK GDPR) (collectively, GDPR), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018), Australia's Privacy Act, and India's Information Technology Act and supplementary rules, impose strict requirements for processing personal data. The EU GDPR and UK GDPR govern the collection, use, disclosure, transfer or other processing of personal data of European Economic Area (EEA) and UK residents, respectively. Among other things, the EU GDPR and UK GDPR impose requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities, stipulate the lawful bases on which personal data can be processed, establish broad definitions of personal data and require changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. The EU GDPR and UK GDPR also provide for substantial fines for breaches and violations (up to the greater of €20 million under the EU GDPR or £17.5 million under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater). The EU GDPR and UK GDPR also confer a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the EU GDPR and UK GDPR.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries including in connection with our clinical trials. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Additionally, the U.S. Department of Justice issued a rule entitled Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restrictions on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or are considered “foreign persons” and majority owned by, organized under the laws of, primarily resident in, or a contractor of a covered person or country of concern, as applicable) that impacts 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.

In addition to data privacy and security laws, we are and may in the future become bound by contractual obligations and industry standards related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies and other statements regarding data privacy and security. Regulators are increasingly scrutinizing these statements, and if these 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.

We increasingly use AI and machine learning tools across our operations and business functions, and we expect our use of such tools to expand over time. While we believe that the responsible use of AI tools can enhance our operational efficiency, these tools present risks that could adversely affect our business. AI-generated outputs may be inaccurate, incomplete, or misleading, and reliance on such outputs could result in errors in regulatory submissions as well as clinical or scientific analyses, non-compliance with relevant obligations (such as laws and contracts), and/or necessitate public disclosures. In addition, the input of proprietary, confidential, or sensitive information into third-party AI platforms could result in the inadvertent disclosure of trade secrets, attorney-client privileged materials, or material nonpublic information. The regulatory landscape governing the use of AI, including in the life sciences and pharmaceutical industries, is rapidly evolving, and such developments could impose additional compliance obligations and costs, restrict certain uses of AI tools, and/or increase our exposure to regulatory enforcement actions or litigation. Any failure to adequately govern our use of AI tools could result in reputational harm, regulatory scrutiny, legal liability and other adverse consequences.

Obligations related to data privacy and security (and consumers’ data privacy obligations) are quickly changing, becoming increasingly stringent, and creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Monitoring, preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations have in the past and may in the future necessitate changes to our information technologies, systems and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change aspects of our business model or our clinical trials.

Although we endeavor to comply with applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we (or third parties with whom we work) fail, or are perceived to have failed, to address or comply with data privacy, protection and security obligations, we could face significant consequences, including (without limitation): government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; and/or imprisonment of company officials. In particular, plaintiffs have become increasingly active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for significant statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including our 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.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our vendors and suppliers, could be subject to power shortages, telecommunications failures, water shortages, civil unrest, labor disputes, violence, earthquakes, floods, hurricanes, typhoons, fires, extreme weather conditions, infectious disease, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We currently rely on third-party suppliers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to initiate or continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we continue to have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our common stock or issue other unfavorable commentary or research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

<u>Independent Auditor's Report</u>	1
<u>Consolidated Balance Sheets as of December 31, 2025 and 2024</u>	3
<u>Consolidated Statements of Operations and Comprehensive Loss for the Year Ended December 31, 2025 and for the period from April 8, 2024 (Inception) to December 31, 2024</u>	4
<u>Consolidated Statements of Stockholders' Deficit for the Year Ended December 31, 2025 and for the period from April 8, 2024 (Inception) to December 31, 2024</u>	5
<u>Consolidated Statements of Cash Flows for the Year Ended December 31, 2025 and for the period from April 8, 2024 (Inception) to December 31, 2024</u>	6
<u>Notes to Consolidated Financial Statements</u>	7

Report of Independent Auditor

To the Board of Directors
Vidya Therapeutics, Inc.
Encinitas, California

Opinion

We have audited the accompanying consolidated financial statements of Vidya Therapeutics, Inc. (the “Company”), which comprise the consolidated balance sheets as of December 31, 2025 and 2024 and the related consolidated statements of operations and comprehensive loss, changes in stockholders’ deficit, and cash flows for the year ended December 31, 2025 and for the period from April 8, 2024 (inception) to December 31, 2024, and the related notes to the consolidated financial statements.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024 and the results of its operations and its cash flows for the periods then ended, in accordance with accounting principles generally accepted in the United States of America.

Basis for Opinion

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Our responsibilities under those standards are further described in the *Auditor’s Responsibilities for the Audit of the Consolidated Financial Statements* section of our report. We are required to be independent of the Company and to meet our other ethical responsibilities in accordance with the relevant ethical requirements relating to our audit. We believe the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Substantial Doubt of the Company’s Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred net losses since its inception which has resulted in a cumulative deficit as of December 31, 2025 that raises substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1.

Other Matter – Change in Control

As discussed in Note 10 to the consolidated financial statements, the Company entered into a Merger agreement with Processa Pharmaceuticals, Inc. (“Processa”) on July 28, 2026 whereby Processa acquired the Company in an all-stock transaction.

Responsibilities of Management for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, management is required to evaluate whether there are conditions or 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 the consolidated financial statements are available to be issued.

Auditor's Responsibilities for the Audit of the Consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not absolute assurance and, therefore, is not a guarantee that an audit conducted in accordance with generally accepted auditing standards will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the consolidated financial statements.

In performing an audit in accordance with generally accepted auditing standards, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the consolidated financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control related matters that we identified during the audit.

/s/ Cherry Bekaert LLP

Waltham, Massachusetts
October 5, 2026

VIDYA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,851	\$ 31
Prepaid expenses and other assets	420	5
Total current assets	<u>3,271</u>	<u>36</u>
Total assets	<u><u>\$ 3,271</u></u>	<u><u>36</u></u>
Liabilities and Stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 155	\$ 76
Accrued expenses	685	-
Total current liabilities	<u>840</u>	<u>76</u>
SAFE liabilities, noncurrent	9,003	411
Total liabilities	<u>9,843</u>	<u>487</u>
Commitments and contingencies (Note 8)		
Stockholders' deficit:		
Common stock, \$0.00001 par value; 1,000,000 shares authorized at December 31, 2025 and December 31, 2024; 643,302 and 624,744 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	-	-
Accumulated other comprehensive loss	(60)	-
Accumulated deficit	<u>(6,512)</u>	<u>(451)</u>
Total stockholders' deficit	<u>(6,572)</u>	<u>(451)</u>
Total liabilities and stockholders' deficit	<u><u>\$ 3,271</u></u>	<u><u>36</u></u>

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

VIDYA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands)

	Year Ended December 31, 2025	Period from April 8, 2024 (Inception) to December 31, 2024
Operating expenses:		
Research and development	\$ 2,818	\$ 307
General and administrative	487	128
Total operating expenses	<u>3,305</u>	<u>435</u>
Loss from operations	(3,305)	(435)
Other income (expense), net:		
Interest income	136	—
Change in fair value of SAFE liabilities	<u>(2,892)</u>	<u>(16)</u>
Total other income (expense), net	(2,756)	(16)
Net loss	<u>\$ (6,061)</u>	<u>\$ (451)</u>
Foreign currency translation	(60)	—
Comprehensive loss	<u>\$ (6,121)</u>	<u>\$ (451)</u>

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

VIDYA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(In thousands, except share amounts)

	Common Stock		Accumulated Other Comprehensive	Accumulated	Total
	Shares	Amount	Loss	Deficit	Stockholders' Deficit
Balance at April 8, 2024 (Inception)	—	\$ —	\$ —	\$ —	\$ —
Issuance of common stock	600,000	—	—	—	—
Issuance of restricted stock awards	24,744	—	—	—	—
Net loss	—	—	—	(451)	(451)
Balance at December 31, 2024	<u>624,744</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ (451)</u>	<u>\$ (451)</u>
Issuance of restricted stock awards	18,558	—	—	—	—
Foreign currency translation	—	—	(60)	—	(60)
Net loss	—	—	—	(6,061)	(6,061)
Balance at December 31, 2025	<u>643,302</u>	<u>\$ —</u>	<u>\$ (60)</u>	<u>\$ (6,512)</u>	<u>\$ (6,572)</u>

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

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

	Year Ended December 31, 2025	Period from April 8, 2024 (Inception) to December 31, 2024
Cash flows from operating activities:		
Net loss	\$ (6,061)	\$ (451)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	—	250
Change in fair value of SAFE liabilities	2,892	16
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(415)	(5)
Accounts payable	79	76
Accrued expenses	685	—
Net cash used in operating activities	<u>(2,820)</u>	<u>(114)</u>
Cash flows from investing activities:		
Cash paid for acquired in-process research and development	—	(250)
Net cash used in investing activities	<u>—</u>	<u>(250)</u>
Cash flows from financing activities:		
Proceeds from issuance of SAFE notes	5,700	395
Net cash provided by financing activities	<u>5,700</u>	<u>395</u>
Effect of exchange rate changes on cash and cash equivalents	(60)	-
Net increase in cash and cash equivalents	<u>2,820</u>	<u>31</u>
Cash and cash equivalents, beginning of period	31	-
Cash and cash equivalents, end of period	<u>\$ 2,851</u>	<u>\$ 31</u>

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

VIDYA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business and Basis of Presentation

Background and Basis of Presentation

Vidya Therapeutics, Inc. and subsidiaries (“Vidya” or the “Company”) was incorporated as a Delaware Corporation on April 8, 2024. The Company is a clinical-stage biotechnology company. The Company is advancing a potentially best-in-class BTK inhibitor (BTKi) designed to improve on the efficacy and safety of early-generation programs. The Company acquired its intellectual property (“IP”) patent portfolio in connection with the Gossamer transaction (see Note 7) and currently has three parallel development programs: food allergy and chronic spontaneous urticaria in immunology, and relapsing multiple sclerosis in neurology, where its central nervous system-penetrant profile addresses an area of high unmet need.

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, the ability to complete preclinical and clinical trials, the ability to obtain regulatory approval for product candidates, development by competitors of new technological innovations, dependence on key personnel, the ability to attract and retain qualified employees, reliance on third-party organizations, protection of proprietary technology, compliance with government regulations, product liability, uncertainty of market acceptance of products and the ability to raise additional capital to fund operations.

The Company’s potential product candidates will require approval from the U.S. Federal Food and Drug Administration or comparable foreign authorities prior to the commencement of commercial sales. There can be no assurance that the Company’s potential product candidates will receive all the required approvals. In addition, there can be no assurance that the Company’s potential product candidates, if approved, will be accepted in the marketplace, that any future product candidates can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such product candidates will be successfully marketed, if at all.

The accompanying consolidated financial statements and accompanying notes include accounts of the Company and its wholly owned subsidiaries, Vidya Therapeutics Australia Pty. Ltd. and GB005, Inc., and have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). All intercompany amounts are eliminated in consolidation.

Going Concern

The Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within twelve months of the date that the consolidated financial statements are issued.

Since its inception, the Company has generated no revenue and has funded its operations primarily through the issuance of Simple Agreements for Future Equity (“SAFEs”) to accredited investors. The Company has incurred recurring operating losses and negative cash flows from operations since inception, including a net loss of \$6.1 million for the year ended December 31, 2025 and had an accumulated deficit of \$6.5 million as of December 31, 2025. The Company expects to continue to incur operating losses and negative cash flows from operations for the foreseeable future as it continues to advance its research and development activities.

The Company’s existing cash and cash equivalents that were primarily raised from SAFEs financings will not be sufficient to fund the Company’s operating plans for at least twelve months from the date these consolidated financial statements are available to be issued. Accordingly, management determined that conditions existed that raised substantial doubt about the Company’s ability to continue as a going concern.

In order to mitigate these conditions, on July 28, 2026, the Company completed a merger with Processa Pharmaceuticals, Inc. (“Processa”). Concurrent with the closing of the Merger (as defined in Note 10), Processa completed a private placement financing that generated gross proceeds of approximately \$200.0 million through the issuance of Processa Series A Non-Voting Convertible Preferred Stock (“Series A Preferred Stock”). In connection with the Merger, holders of the Company’s equity securities received Series A Preferred Stock, and the Company’s outstanding options were assumed or exchanged for corresponding options to purchase an aggregate of 1,047,524 shares of Processa common stock (the “Assumed Options”).

VIDYA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Processa Series A Preferred Stock issued in the Merger and the private placement financing are convertible into Processa common stock, subject to receiving approval by Processa's stockholders of the issuance of shares of its common stock upon conversion of Series A Preferred Stock and exercise of the Assumed Options, which (a) will represent more than 20% of the shares of Processa's common stock outstanding pursuant to Nasdaq Listing Rule 5635(a) and (b) may, together with certain changes to Processa's management and board of directors, result in a change of control of Processa pursuant to Nasdaq Listing Rule 5635(b) (the "Conversion Proposal") and certain beneficial ownership limitations set by each holder. Under the terms of the Certificate of Designation of Preferences, Rights and Limitations of the Series A Preferred Stock (the "Certificate of Conversion"), if Processa fails to deliver to the holder of the Series A Preferred Stock shares of its common stock underlying such shares of Series A Preferred Stock at any time nine months after the initial issuance of the Series A Preferred Stock, holders of the Series A Preferred Stock are entitled to require Processa to make cash payments by wire transfer of immediately available funds equal to the Fair Value (as defined in the Certificate of Designation) of such undelivered shares. As a result, the Company concluded that the proceeds received from the private placement financing cannot be relied upon to mitigate the conditions that raised substantial doubt because the availability of those proceeds is subject to conditions that are not entirely within the Company's control. Management's plan to convert the Series A Preferred Stock into common stock and therefore remove the requirement to make cash payment based on the value of the undelivered shares is the execution of a stockholder proxy vote set to take place in the first quarter of 2027. Accordingly, the Company concluded that substantial doubt about the Company's ability to continue as a going concern continues to exist within one year after the date these financial statements are available to be issued.

The financial statements do not include any adjustments relating to the recoverability and classification of recorded assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Principles of Consolidation

In May 2024, the Company formed GB005, Inc., which is a wholly owned subsidiary in the United States. In May 2025, the Company formed Vidya Therapeutics Australia Pty Ltd, which is a wholly owned subsidiary based in Australia. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, assumptions, and judgements that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected within these consolidated financial statements include but are not limited to research and development expenses and related prepaid or accrued costs, the valuation of stock-based awards, and the valuation of SAFEs and related expenses. The Company bases its estimates on known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in circumstances, facts, and experience. Actual results may differ materially from those estimates or assumptions.

Concentrations of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash and cash equivalents. The Company maintains its cash balances at an accredited financial institution in amounts that, at times, may exceed federally insured limits. However, the Company has not experienced any losses on its deposits of cash.

VIDYA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company is dependent on third-party organizations to research, develop, manufacture, and process its potential product candidates for its development programs. The Company expects to continue to be dependent on a small number of manufacturers to supply it with its requirements for all products. The Company's research and development programs could be adversely affected by a significant interruption in the supply of the necessary materials.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less at the time of initial purchase to be cash equivalents. The cash equivalents were comprised of an investment in a money market fund. Interest income associated with the cash equivalents is recorded as other income in the consolidated statements of operations and comprehensive loss.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' deficit that result from transactions and events other than those with stockholders. The Company's unrealized foreign exchange fluctuations represent the only components of other comprehensive loss that are excluded from the reported net loss and that are presented in the consolidated statements of operations and comprehensive loss.

Foreign Currency and Currency Translation

Assets and liabilities in foreign currency amounts are translated into United States dollars at the exchange rate in effect on the consolidated balance sheet date as a result of our Australian foreign subsidiary with a functional currency of the Australian Dollar. Income and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a translation adjustment, which is included as a separate component of stockholders' deficit. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the functional currency are included in the Company's consolidated statements of operations and comprehensive loss.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets that are identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

The Company's cash equivalents and SAFE liability are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company's prepaid expenses, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities.

VIDYA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SAFE Liability

During the period from April 8, 2024 (inception) to December 31, 2024, the Company issued SAFEs to investors totaling \$0.4 million, which afforded the investors the right to future equity of the Company based on the occurrence of certain triggering events. During the year ended December 31, 2025, the Company issued additional SAFEs to investors totaling \$5.7 million. The Company classified the SAFEs as a liability on its consolidated balance sheets as it is considered a freestanding financial instrument that is neither an outstanding share nor debt, and the Company may be required to transfer assets to settle the instrument. The SAFE liability is initially recorded at fair value upon the issuance date and is subsequently remeasured at each reporting date until the SAFE's are cash settled or convert to equity. Changes in fair value of the SAFE liability are recognized as a component of other income (expense), net in the Company's consolidated statements of operations and comprehensive loss.

Research and Development Contract Costs Accruals

The Company records the costs associated with research studies and manufacturing development as incurred. These costs are a significant component of the Company's research and development expenses, with a substantial portion of the Company's ongoing research and development activities conducted by third-party service providers, including contract research organizations ("CRO's").

The Company accrues for expenses resulting from obligations under its agreements with CROs and other outside service providers for which payment flows do not match the periods over which materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with CROs and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services. The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. In the event advance payments are made to CRO or outside service provider, the payments will be recorded as a prepaid asset which will be expensed as the contracted services are performed. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include consulting, laboratory expenses, clinical trial expenses, insurance expenses, and drug expenses related to chemicals, manufacturing, and controls. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

Research and Development Tax Incentives

The Company's Australian subsidiary participates in the Australian Government's Research and Development Tax Incentive ("RDTI") program. Entities with aggregated turnover below AUD \$20 million are entitled to a refundable tax offset equal to a specified percentage of eligible research and development expenditure incurred during the applicable Australian income year (July 1st to June 30th).

Because entitlement to the RDTI offset does not depend on the Company's income tax position, the Company does not account for these amounts under ASC 740, Income Taxes. In the absence of authoritative U.S. GAAP guidance addressing government assistance provided to for-profit business entities, the Company has adopted an accounting policy analogizing to the conditional contribution guidance in ASC 958-605, Not-for-Profit Entities—Revenue Recognition.

Under this policy, the RDTI offset is evaluated as containing a measurable performance-related barrier, substantiation, through a technical qualification analysis, that expenditures incurred meet the statutory definition of eligible R&D activities. The Company recognizes the RDTI benefit as a reduction of research and development expense with an offsetting receivable on the date the qualifying technical analysis is completed, rather than at the end of the related Australian income year or upon receipt of cash.

VIDYA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the year ended December 31, 2025, the Company recognized \$0.1 million of RDTI benefit related to its Australian subsidiary's income tax year ended June 30, 2025, based on completion of the qualifying analysis in 2025. No amount was recognized as of December 31, 2025 related to the income tax year ended June 30, 2026, as the related qualifying analysis had not yet been completed as of that date.

General and Administrative Expenses

General and administrative expenses consist primarily of consulting, contract labor, and legal fees.

Commitments and Contingencies

The Company may be subject to contingent liabilities, such as legal proceedings and claims, that arise in the ordinary course of business activities. The Company accrues for loss contingencies when losses become probable and are reasonably estimable. If the reasonable estimate of the loss is a range and no amount within the range is a better estimate, the minimum amount of the range is recorded as a liability on the consolidated balance sheet. The Company does not accrue for contingent losses that, in its judgment, are considered to be reasonably possible, but not probable; however, it discloses the range of reasonably possible losses. As of December 31, 2025 and 2024, no liabilities were recorded for loss contingencies (see Note 8).

Stock-Based Compensation

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The Company grants restricted stock awards ("RSAs") that are subject to service-based vesting conditions. Compensation expense for awards to non-employees with service-based vesting conditions is recognized in the same manner as if the Company had paid cash in exchange for the goods or services.

The fair value of RSAs are based on the fair value of the Company's common stock on the date of grant. The Company's common stock valuations are determined by the board of directors, with input from management and third-party valuations, as there was no public market for the common stock.

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

Income Taxes

Income tax expense is the total of the current year income tax due or refundable and the change in deferred tax assets and liabilities. Deferred tax assets and liabilities are the expected future tax amounts, computed using enacted tax rates, attributable to temporary differences between carrying amounts and tax bases of assets and liabilities and to carryforwards of tax deductions or credits. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment. The Company recognizes interest and penalties related to unrecognized tax benefits as a component of income tax expense. The Company has determined that it does not have any material unrecognized tax benefits or obligations as of December 31, 2025 and 2024, therefore no such interest or penalties were recognized during the periods presented.

VIDYA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Recently Issued Accounting Pronouncement Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses (“ASU 2024-03”). The amendments in ASU 2024-03 require public entities to disclose specified information about certain costs and expenses. ASU 2024-03 is effective for the Company’s annual reporting period beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which focuses on the rate reconciliation and income taxes paid. ASU No. 2023-09 requires a public business entity (PBE) to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. For PBEs, the new standard is effective for annual periods beginning after December 15, 2024, with early adoption permitted. For entities other than PBEs, the requirements will be effective for annual periods beginning after December 15, 2025. An entity may apply the amendments in this ASU prospectively by providing the revised disclosures for the period ending December 31, 2025 and continuing to provide the pre-ASU disclosures for the prior periods, or may apply the amendments retrospectively by providing the revised disclosures for all period presented. The Company has adopted ASU 2023-09 for the year ended December 31, 2025 and has retrospectively applied the disclosures for the year ended December 31, 2024. The adoption of ASU 2023-09 had no impact to the Company’s financial position, results of operations, or cash flows.

3. Fair Value Measurements

The following tables present the Company’s fair value hierarchy for financial assets and liabilities measured at fair value on a recurring basis (in thousands):

December 31, 2025				
	Level 1	Level 2	Level 3	Total
Assets:				
Money market fund	\$ 2,620	\$ -	\$ -	\$ 2,620
Total assets	\$ 2,620	\$ -	\$ -	\$ 2,620
Liabilities:				
SAFE Liability	\$ -	\$ -	\$ 9,003	\$ 9,003
Total liabilities	\$ -	\$ -	\$ 9,003	\$ 9,003
December 31, 2024				
	Level 1	Level 2	Level 3	Total
Liabilities:				
SAFE Liability	\$ -	\$ -	\$ 411	\$ 411
Total liabilities	\$ -	\$ -	\$ 411	\$ 411

Cash equivalents consist of money market funds, which were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. There were no transfers between Level 1, Level 2, or Level 3 during the year ended December 31, 2025 and during the period from April 8, 2024 (Inception) to December 31, 2024.

VIDYA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Valuation of SAFE Liability

The following table provides a roll-forward of the aggregate fair values of the Company's SAFE liability, for which fair value was determined by Level 3 inputs (in thousands):

Balance as of April 8, 2024 (Inception)	\$ -
Issuance of SAFEs	395
Change in fair value of SAFEs	16
Balance as of December 31, 2024	\$ 411
Issuance of SAFEs	5,700
Change in fair value of SAFEs	2,892
Balance as of December 31, 2025	\$ 9,003

The SAFE liability in the table above consisted of the fair value of the SAFEs to convert into future equity of the Company and was based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

The Company's valuation of the SAFE liability utilizes a scenario-based valuation analysis that incorporates assumptions and estimates, including the probability and timing of future financing or liquidity events, the estimated value of the Company's equity, expected volatility, and the contractual terms of the SAFEs. The SAFEs contain a contractual valuation cap of \$25.0 million and an 85% discount rate. Upon a qualifying equity financing, the SAFEs convert at a conversion price based on the more favorable of the price derived from the \$25.0 million valuation cap or the applicable discounted financing price. The valuation cap is also used in determining the conversion amount in the event of a liquidity event. The Company considers the economic impact of these contractual features in estimating the fair value of the SAFE liability and reassesses the significant assumptions and estimates at each reporting date as additional information becomes available.

The following table presents the assumptions and estimates incorporated into the valuation of the SAFE liability:

	12/31/2025	12/31/2024
Estimated equity value of the Company (in thousands)	\$ 38,240	\$ 25,020
Expected volatility	90.0%	80.0%
Time to Next Equity Financing (in years)	0.48	1.00
Probability of Next Equity Financing	90.0%	85.0%
Discount Rate	39.0%	22.5%

4. Common Stock

As of December 31, 2025 and 2024, the Company has the authority to issue a total of 1,000,000 shares of common stock, at a par value of \$0.00001 per share. As of December 31, 2025 and 2024, the Company had 643,302 and 624,744 shares of common stock, respectively, issued and outstanding in connection with the issuance of common stock and RSAs. Unvested RSAs are considered legally issued and outstanding shares of common stock. Each share of common stock entitles the holder to one vote, on all matters submitted to the stockholders for a vote. The holders of common stock are entitled to receive dividends, if any, as declared by the Company's Board of Directors.

VIDYA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

5. Stock-based Compensation

2025 Equity Incentive Plan

On April 4, 2025, the Board of Directors approved the 2025 Equity Incentive Plan (the “2025 Plan”), under which the Company may grant incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards to employees, officers, directors, consultants, and advisors. The 2025 Plan is administered by the Board of Directors, or, at the discretion of the Board of Directors, by a committee of the Board of Directors. The exercise prices, vesting and other restrictions are determined at the discretion of the Board of Directors, or its committee, if so delegated. Stock awards granted under the 2025 Plan generally vest in differing periodic installments and expire after ten years. Upon adoption, the 2025 Plan authorized 71,478 shares of common stock reserved for issuance under the plan. No awards have been issued under the 2025 plan as of December 31, 2025.

Restricted Stock Awards

During the period from April 8, 2024 (inception) to December 31, 2024 and during the year ended December 31, 2025, the Company issued and sold 24,744 and 18,558 RSAs, respectively, to certain non-employees, directors, and consultants at a purchase price of \$0.0001 per share. Such RSAs have service-based vesting conditions only and vest over a four-year period, during which time all unvested shares are subject to forfeiture by the Company in the event the holder’s service with the Company voluntarily or involuntarily terminates.

The following table summarizes the RSA activity for the year ended December 31, 2025:

Restricted Stock Awards

	RSAs	Weighted Average Grant Date Fair Value
Unvested balance as of December 31, 2024	20,102	\$ -
Granted	18,558	-
Vested	(12,243)	-
Unvested balance as of December 31, 2025	<u>26,417</u>	<u>\$ -</u>

6. Income Taxes

The effective tax rate differs from the statutory rate primarily due to an increase in the valuation allowance and permanent differences related to fair value adjustments on the Company’s SAFE liabilities. The Company uses the cash basis for income tax purposes and the accrual basis for financial reporting, which gives rise to temporary differences recorded as deferred taxes. The SAFE liabilities are recorded at fair value under U.S. GAAP, with changes in fair value recognized in earnings. The Company treats the SAFE liabilities as equity for income tax purposes; accordingly, changes in fair value are not included in taxable income and are treated as permanent differences.

The Company recorded no income tax expense or benefit for the years ended December 31, 2025 and 2024, as there was no current tax expense in any jurisdiction and the deferred tax benefit arising in each year was fully offset by an increase in the valuation allowance. Accordingly, the Company’s effective tax rate was 0% for both years. State and local income taxes in California make up the majority (greater than 50%) of the Company’s state income taxes.

(Loss) before income taxes are as follows (in thousands):

	Year Ended December 31, 2025	Period from April 8, 2024 (Inception) to December 31, 2024
U.S.	\$ (4,046)	\$ (451)
Australia	(2,015)	-
Total (loss) before income taxes	<u>\$ (6,061)</u>	<u>\$ (451)</u>

VIDYA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The components of deferred income taxes as of December 31, 2025 and 2024, were as follows (in thousands):

	December 31, 2025	December 31, 2024
Deferred tax liabilities		
Prepaid expenses	\$ (8)	\$ (2)
Gross deferred tax liabilities	(8)	(2)
Deferred tax assets		
Net operating loss carryforwards	428	48
Intangible assets - basis differences	62	67
Accrued expenses and accounts payable	64	21
Gross deferred tax assets	554	136
Deferred tax asset valuation allowance	(546)	(134)
Net deferred tax asset	\$ -	\$ -

The Company did not pay any income taxes to federal, state, or foreign jurisdictions during the year ended December 31, 2025 or the period from April 8, 2024 (inception) to December 31, 2024.

At December 31, 2025, the Company has federal net operating loss carryforwards of \$1.5 million that may be offset against future taxable income. These carryforwards have an indefinite carryforward period and, under the Tax Cuts and Jobs Act, may be used to offset only 80% of taxable income in any future year. Australian net operating loss carryforwards are nominal because substantially all of the Company's Australian expenditures relate to activities eligible for RDTI. Under Australian tax law, expenditures claimed under the RDTI are excluded from the calculation of taxable losses.

Section 382 Limitation

The Merger (see Note 10) resulted in a change in ownership of the Company as defined under Section 382 of the Internal Revenue Code. Section 382 imposes an annual limitation on the amount of a corporation's net operating loss carryforwards and other tax attributes that may be utilized to offset future taxable income following such an ownership change.

The Company has not completed a formal study to determine the amount of its net operating loss carryforwards, credit carryforwards, and other tax attributes that may be subject to limitation under Section 382 as a result of the Merger, or as a result of any prior issuances of the Company's equity securities and SAFEs that may have independently resulted in one or more ownership changes. Until such a study is completed, the extent to which the Company's carryforwards may be limited or permanently unavailable is not known.

Because the Company's net deferred tax assets, including its net operating loss and credit carryforwards, are fully offset by a valuation allowance, the Company does not expect any limitation resulting from Section 382 to have an impact on its consolidated financial statements; however, any such limitation could reduce the tax attributes disclosed above that would otherwise be available to offset future taxable income.

7. Gossamer Agreement

In May 2024, the Company entered into a merger agreement with Gossamer Bio, Inc. ("Gossamer") and GB005, Inc., a wholly owned subsidiary of Gossamer (the "Gossamer Agreement"), pursuant to which GB005, Inc. became a wholly owned subsidiary of the Company. Through the transaction, the Company acquired the GB5121 and GB7208 development programs, including the related intellectual property, research data, inventory, and other program assets.

VIDYA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company concluded that the transaction should be accounted for as an asset acquisition rather than a business combination because substantially all of the fair value of the gross assets acquired was concentrated in a group of similar identifiable assets, consisting principally of the acquired in-process research and development (“IPR&D”) programs. The acquired IPR&D assets were determined to have no alternative future use as of the acquisition date because the programs remained in development and significant additional research, development, regulatory, and commercialization activities were required before they could generate future economic benefits. Accordingly, the initial merger consideration of \$0.3 million was allocated to the acquired IPR&D assets and recognized as research and development expense in the consolidated statements of operations and comprehensive loss during the period April 8, 2024 (inception) to December 31, 2024.

The Gossamer Agreement also includes contingent consideration consisting of development, regulatory, commercial, and sales-based milestone payments, annual sales-based earn-out payments tied to future net sales of products utilizing the acquired program assets, and certain acquisition-related payments upon the occurrence of specified qualifying transactions. These contingent payments become payable only upon the occurrence of specified future events. The Merger with Processa that was completed on July 28, 2026 (see Note 10) did not trigger any milestone, earn-out, or other contingent consideration payments in connection with the Gossamer Agreement. As of the acquisition date, no liability was recognized related to the contingent consideration arrangements. Future payments, if any, will be recognized when the applicable contingency is resolved and the related payment obligation arises and will be accounted for based on the nature of the payment and the status of the underlying acquired assets at that time.

8. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may become involved in legal proceedings or other litigation relating to claims arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and estimated exposure amount. Legal fees and other costs associated with such proceedings are expensed as incurred. As of December 31, 2025 and 2024, the Company was not a party to any material legal proceedings or claims.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with each of its directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or executive officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2025.

9. Related Party Transactions

The Company entered into significant related party transactions during 2024 and 2025 related to the issuance of SAFEs (see Note 3). During 2024, the Company issued three SAFEs to its Chief Executive Officer totaling \$0.4 million. During 2025, the Company issued additional SAFEs to related parties, including an entity affiliated with a member of the Company’s Board of Directors, totaling \$2.1 million. The terms and conditions of the SAFEs issued to related parties were the same as those of the SAFEs issued to third-party investors during the respective periods. The Company did not have any other significant related party transactions during the periods presented.

VIDYA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

10. Subsequent Events

The Company has evaluated events and transactions occurring subsequent to December 31, 2025 through October 5, 2026, the date at which the consolidated financial statements are available to be issued.

Stock Option Grants

In February 2026, the Company granted an aggregate of 6,434 stock options to three non-employees under the Company's Equity Incentive Plan. The stock options have an exercise price of \$0.0001 per share and expire on February 10, 2036. The stock options are subject to service-based vesting requirements over approximately four years.

Merger Agreement

On July 28, 2026, the Company completed the transactions contemplated by the Agreement and Plan of Merger (the "Merger Agreement") with Processa and Venus Merger Sub I, Inc. and Venus Merger Sub II, LLC, both wholly owned subsidiaries of Processa. Pursuant to the Merger Agreement, Venus Merger Sub I, Inc. merged with and into Vidya, with Vidya continuing as a wholly owned subsidiary of Processa and the surviving corporation (the "First Merger"). Immediately following the First Merger and as part of the same overall transaction, Vidya merged with and into Venus Merger Sub II, LLC (the "Second Merger" and, together with the First Merger, the "Merger"), with Venus Merger Sub II, LLC being the surviving entity of the Second Merger.

Pursuant to the Merger Agreement, holders of Vidya equity securities, including all unvested RSAs and outstanding SAFEs, received an aggregate of 142,254.972 shares of Series A Preferred Stock. Outstanding Company options were assumed or exchanged for corresponding options to purchase an aggregate of 1,047,524 shares of Processa common stock.

Concurrent with the closing of the Merger, Processa completed a private placement financing with certain investors that generated gross proceeds of approximately \$200.0 million through the issuance of Series A Preferred Stock.

Receipt of Australian Research and Development Tax Incentive Refund

On September 17, 2026, Vidya Therapeutics Australia Pty. Ltd., the Company's wholly owned Australian subsidiary, received a cash refund of approximately \$1.7 million from the Australian Taxation Office related to the Australian RDTI claim for the income tax year ended June 30, 2026.

INDEX TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

<u>Condensed Consolidated Balance Sheets as of June 30, 2026 (Unaudited) and December 31, 2025</u>	2
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the Six Months Ended June 30, 2026 and 2025 (Unaudited)</u>	3
<u>Condensed Consolidated Statements of Stockholders' Deficit for the Six Months Ended June 30, 2026 and 2025 (Unaudited)</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2026 and 2025 (Unaudited)</u>	5
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	6

VIDYA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 245	\$ 2,851
Prepaid expenses and other assets	486	420
Total current assets	<u>731</u>	<u>3,271</u>
Total assets	<u><u>\$ 731</u></u>	<u><u>\$ 3,271</u></u>
Liabilities and Stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 941	\$ 155
Accrued expenses	106	685
SAFE liabilities, current	<u>36,330</u>	<u>-</u>
Total current liabilities	37,377	840
SAFE liabilities, noncurrent	<u>-</u>	<u>9,003</u>
Total liabilities	37,377	9,843
Commitments and contingencies (Note 7)		
Stockholders' deficit:		
Common stock, \$0.00001 par value; 1,000,000 shares authorized at June 30, 2026 and December 31, 2025; 643,302 shares issued and outstanding at June 30, 2026 and December 31, 2025	-	-
Additional paid-in capital	3	-
Accumulated other comprehensive loss	(20)	(60)
Accumulated deficit	<u>(36,629)</u>	<u>(6,512)</u>
Total stockholders' deficit	<u>(36,646)</u>	<u>(6,572)</u>
Total liabilities and stockholders' deficit	<u><u>\$ 731</u></u>	<u><u>\$ 3,271</u></u>

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

VIDYA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(In thousands)

	For the Six Months Ended June 30,	
	2026	2025
Operating expenses:		
Research and development	\$ 2,178	\$ 291
General and administrative	628	203
Total operating expenses	<u>2,806</u>	<u>494</u>
Loss from operations	(2,806)	(494)
Other income (expense), net:		
Interest income	16	51
Change in fair value of SAFE liabilities	(27,327)	(1,656)
Total other income (expense), net	<u>(27,311)</u>	<u>(1,605)</u>
Net loss	<u>\$ (30,117)</u>	<u>\$ (2,099)</u>
Foreign currency translation	40	(2)
Comprehensive loss	<u>\$ (30,077)</u>	<u>\$ (2,101)</u>

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

VIDYA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(UNAUDITED)
(In thousands, except share amounts)

	Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-in	Other	Deficit	Stockholders'
			Capital	Comprehensive		Deficit
				Income (Loss)		
Balance at December 31, 2024	624,744	\$ —	\$ —	\$ —	\$ (451)	\$ (451)
Issuance of restricted stock awards	18,558	—	—	—	—	—
Foreign currency translation	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	(2,099)	(2,099)
Balance at June 30, 2025	<u>643,302</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ (2)</u>	<u>\$ (2,550)</u>	<u>\$ (2,552)</u>
Balance at December 31, 2025	643,302	\$ —	\$ —	\$ (60)	\$ (6,512)	\$ (6,572)
Stock-based compensation expense	—	—	3	—	—	3
Foreign currency translation	—	—	—	40	—	40
Net loss	—	—	—	—	(30,117)	(30,117)
Balance at June 30, 2026	<u>643,302</u>	<u>\$ —</u>	<u>\$ 3</u>	<u>\$ (20)</u>	<u>\$ (36,629)</u>	<u>\$ (36,646)</u>

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

VIDYA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(In thousands)

	For the Six Months Ended June 30,	
	2026	2025
Cash flows from operating activities:		
Net loss	\$ (30,117)	\$ (2,099)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3	-
Change in fair value of SAFE liabilities	27,327	1,656
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(66)	(76)
Accounts payable	786	283
Accrued expenses	(579)	30
Net cash used in operating activities	(2,646)	(206)
Cash flows from financing activities:		
Proceeds from issuance of SAFE notes	—	5,700
Net cash provided by financing activities	—	5,700
Effect of exchange rate changes on cash and cash equivalents	40	(3)
Net (decrease) increase in cash and cash equivalents	(2,606)	5,491
Cash and cash equivalents, beginning of period	2,851	31
Cash and cash equivalents, end of period	<u>\$ 245</u>	<u>\$ 5,522</u>

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

VIDYA THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business and Basis of Presentation

Background and Basis of Presentation

Vidya Therapeutics, Inc. and subsidiaries (“Vidya” or the “Company”) was incorporated as a Delaware Corporation on April 8, 2024. The Company is a clinical-stage biotechnology company. The Company is advancing a potentially best-in-class BTK inhibitor (BTKi) designed to improve on the efficacy and safety of early-generation programs. The Company currently has three parallel development programs: food allergy and chronic spontaneous urticaria in immunology, and relapsing multiple sclerosis in neurology, where its central nervous system-penetrant profile addresses an area of high unmet need.

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, the ability to complete preclinical and clinical trials, the ability to obtain regulatory approval for product candidates, development by competitors of new technological innovations, dependence on key personnel, the ability to attract and retain qualified employees, reliance on third-party organizations, protection of proprietary technology, compliance with government regulations, product liability, uncertainty of market acceptance of products and the ability to raise additional capital to fund operations.

The Company’s potential product candidates will require approval from the U.S. Federal Food and Drug Administration or comparable foreign authorities prior to the commencement of commercial sales. There can be no assurance that the Company’s potential product candidates will receive all the required approvals. In addition, there can be no assurance that the Company’s potential product candidates, if approved, will be accepted in the marketplace, that any future product candidates can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such product candidates will be successfully marketed, if at all.

The accompanying condensed consolidated financial statements and accompanying notes include accounts of the Company and its wholly owned subsidiaries, Vidya Therapeutics Australia Pty. Ltd. and GB005, Inc., and have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). All intercompany amounts are eliminated in consolidation.

Going Concern

The Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within twelve months of the date that the condensed consolidated financial statements are issued.

Since its inception, the Company has generated no revenue and has funded its operations primarily through the issuance of Simple Agreements for Future Equity (“SAFEs”) to accredited investors. The Company has incurred recurring operating losses and negative cash flows from operations since inception, including a net loss of \$30.1 million for the six months ended June 30, 2026, and had an accumulated deficit of \$36.6 million as of June 30, 2026. The Company expects to continue to incur operating losses and negative cash flows from operations for the foreseeable future as it continues to advance its research and development activities.

The Company’s existing cash and cash equivalents that were primarily raised from SAFEs financings will not be sufficient to fund the Company’s operating plans for at least twelve months from the date these condensed consolidated financial statements are available to be issued. Accordingly, management determined that conditions existed that raised substantial doubt about the Company’s ability to continue as a going concern.

In order to mitigate these conditions, on July 28, 2026, the Company completed a merger with Processa Pharmaceuticals, Inc. (“Processa”). Concurrent with the closing of the Merger (as defined in Note 10), Processa completed a private placement financing that generated gross proceeds of approximately \$200.0 million through the issuance of Processa Series A Non-Voting Convertible Preferred Stock (“Series A Preferred Stock”). In connection with the Merger, holders of the Company’s equity securities received Series A Preferred Stock, and the Company’s outstanding options were assumed or exchanged for corresponding options to purchase an aggregate of 1,047,524 shares of Processa common stock (the “Assumed Options”).

VIDYA THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Processa Series A Preferred Stock issued in the Merger and the private placement financing are convertible into Processa common stock, subject to receiving approval by Processa's stockholders of the issuance of shares of its common stock upon conversion of Series A Preferred Stock and exercise of the Assumed Options, which (a) will represent more than 20% of the shares of Processa's common stock outstanding pursuant to Nasdaq Listing Rule 5635(a) and (b) may, together with certain changes to Processa's management and board of directors, result in a change of control of Processa pursuant to Nasdaq Listing Rule 5635(b) (the "Conversion Proposal") and certain beneficial ownership limitations set by each holder. Under the terms of the Certificate of Designation of Preferences, Rights and Limitations of the Series A Preferred Stock (the "Certificate of Conversion"), if Processa fails to deliver to the holder of the Series A Preferred Stock shares of its common stock underlying such shares of Series A Preferred Stock at any time nine months after the initial issuance of the Series A Preferred Stock, holders of the Series A Preferred Stock are entitled to require Processa to make cash payments by wire transfer of immediately available funds equal to the Fair Value (as defined in the Certificate of Designation) of such undelivered shares. As a result, the Company concluded that the proceeds received from the private placement financing cannot be relied upon to mitigate the conditions that raised substantial doubt because the availability of those proceeds is subject to conditions that are not entirely within the Company's control. Management's plan to convert the Series A Preferred Stock into common stock and therefore remove the requirement to make cash payment based on the value of the undelivered shares is the execution of a stockholder proxy vote set to take place in the first quarter of 2027. Accordingly, the Company concluded that substantial doubt about the Company's ability to continue as a going concern continues to exist within one year after the date these financial statements are available to be issued.

The financial statements do not include any adjustments relating to the recoverability and classification of recorded assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in Note 2 to its audited financial statements as of and for the year ended December 31, 2025 and as of December 31, 2024 and for the period from April 8, 2024 (inception) to December 31, 2024 and the related notes. Since the date of those financial statements, there have been no changes to the Company's significant accounting policies except as noted below.

Research and Development Tax Incentives

The Company's Australian subsidiary participates in the Australian Government's Research and Development Tax Incentive ("RDTI") program. Entities with aggregated turnover below AUD \$20 million are entitled to a refundable tax offset equal to a specified percentage of eligible research and development expenditure incurred during the applicable Australian income year (July 1st to June 30th).

Because entitlement to the RDTI offset does not depend on the Company's income tax position, the Company does not account for these amounts under ASC 740, Income Taxes. In the absence of authoritative U.S. GAAP guidance addressing government assistance provided to for-profit business entities, the Company has adopted an accounting policy analogizing to the conditional contribution guidance in ASC 958-605, Not-for-Profit Entities—Revenue Recognition.

Under this policy, the RDTI offset is evaluated as containing a measurable performance-related barrier, substantiation, through a technical qualification analysis, that expenditures incurred meet the statutory definition of eligible R&D activities. The Company recognizes the RDTI benefit as a reduction of research and development expense with an offsetting receivable on the date the qualifying technical analysis is completed, rather than at the end of the related Australian income year or upon receipt of cash.

The Company did not recognize any RDTI benefit during the six months ended June 30, 2026. Subsequent to June 30, 2026, the Company completed its qualification analysis and recognized approximately \$1.7 million of RDTI benefit related to its Australian subsidiary's income tax year ended June 30, 2026 (see Note 9).

VIDYA THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Stock Options

The fair value of each stock option grant is estimated on the grant date using the Black-Scholes option-pricing model. The Company is a private company and lacks company-specific historical and implied volatility information. The Company estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" stock options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Recently Issued Accounting Pronouncement Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03"). The amendments in ASU 2024-03 require public entities to disclose specified information about certain costs and expenses. ASU 2024-03 is effective for the Company's annual reporting period beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of this standard on its condensed consolidated financial statements.

3. Fair Value Measurements

The following tables present the Company's fair value hierarchy for financial assets and liabilities measured at fair value on a recurring basis (in thousands):

June 30, 2026				
	Level 1	Level 2	Level 3	Total
Liabilities:				
SAFE Liability	\$ -	\$ -	\$ 36,330	\$ 36,330
Total liabilities	\$ -	\$ -	\$ 36,330	\$ 36,330
December 31, 2025				
	Level 1	Level 2	Level 3	Total
Assets:				
Money market fund	\$ 2,620	\$ -	\$ -	\$ 2,620
Total assets	\$ 2,620	\$ -	\$ -	\$ 2,620
Liabilities:				
SAFE Liability	\$ -	\$ -	\$ 9,003	\$ 9,003
Total liabilities	\$ -	\$ -	\$ 9,003	\$ 9,003

As of June 30, 2026 the Company did not hold any cash equivalents. Cash equivalents as of December 31, 2025 consisted of money market funds, which were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. There were no transfers between Level 1, Level 2, or Level 3 during the six months ended June 30, 2026.

VIDYA THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Valuation of SAFE Liability

The following table provides a roll-forward of the aggregate fair values of the Company's SAFE liability, for which fair value was determined by Level 3 inputs (in thousands):

Balance as of December 31, 2024	\$ 411
Issuance of SAFEs	5,700
Change in fair value of SAFEs	1,656
Balance as of June 30, 2025	\$ 7,767
Balance as of December 31, 2025	\$ 9,003
Change in fair value of SAFEs	27,327
Balance as of June 30, 2026	\$ 36,330

The SAFE liability in the table above consisted of the fair value of the SAFEs to convert into future equity of the Company and was based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

The Company's valuation of the SAFE liability utilizes a scenario-based valuation analysis that incorporates assumptions and estimates, including the probability and timing of future financing or liquidity events, the estimated value of the Company's equity, expected volatility, and the contractual terms of the SAFEs. The SAFEs contain a contractual valuation cap of \$25.0 million and an 85% discount rate. Upon a qualifying equity financing, the SAFEs convert at a conversion price based on the more favorable of the price derived from the \$25.0 million valuation cap or the applicable discounted financing price. The valuation cap is also used in determining the conversion amount in the event of a liquidity event. The Company considers the economic impact of these contractual features in estimating the fair value of the SAFE liability and reassesses the significant assumptions and estimates at each reporting date as additional information becomes available.

The increase in the fair value of the SAFE liabilities during the six months ended June 30, 2026 was primarily attributable to an increase in the estimated fair value of the Company's equity. As of June 30, 2026, the Company estimated its equity value based on the implied value derived from the pending merger with Processa (see Note 9), resulting in an estimated equity value of approximately \$175.0 million. This represented a change from the valuation methodology utilized as of December 31, 2025 and resulted in a significant increase in the estimated equity value used in the SAFE valuation. The higher estimated equity value contributed to a corresponding increase in the fair value of the SAFE liabilities during the six months ended June 30, 2026.

The following table presents the assumptions and estimates incorporated into the valuation of the SAFE liability:

	6/30/2026	6/30/2025
Estimated equity value of the Company (in thousands)	\$ 175,000	\$ 31,130
Expected volatility	62.5%	95.0%
Time to Next Equity Financing (in years)	0.08	0.75
Probability of Next Equity Financing	95.0%	95.0%
Discount Rate	40.5%	39.0%

4. Common Stock

As of June 30, 2026 and December 31, 2025, the Company has the authority to issue a total of 1,000,000 shares of common stock, at a par value of \$0.00001 per share. As of June 30, 2026 and December 31, 2025, the Company had 643,302 shares of common stock issued and outstanding in connection with the issuance of common stock and RSAs. Unvested RSAs are considered legally issued and outstanding shares of common stock. Each share of common stock entitles the holder to one vote, on all matters submitted to the stockholders for a vote. The holders of common stock are entitled to receive dividends, if any, as declared by the Company's Board of Directors. As of June 30, 2026, the Company reserved 6,434 shares of common stock for the exercise of stock options to common stock.

VIDYA THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

5. Stock-based Compensation

2025 Equity Incentive Plan

On April 4, 2025, the Board of Directors approved the 2025 Equity Incentive Plan (the “2025 Plan”), under which the Company may grant incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards to employees, officers, directors, consultants, and advisors. The 2025 Plan is administered by the Board of Directors, or, at the discretion of the Board of Directors, by a committee of the Board of Directors. The exercise prices, vesting and other restrictions are determined at the discretion of the Board of Directors, or its committee, if so delegated. Stock awards granted under the 2025 Plan generally vest in differing periodic installments and expire after ten years. As of June 30, 2026, the total number of shares of common stock reserved for issuance under the 2025 Plan was 71,478 shares, with 65,044 shares of common stock available for future grants.

Restricted Stock Awards

The following table summarizes the RSA activity for the six months ended June 30, 2026:

	<u>Number of RSAs</u>	<u>Weighted Average Grant Date Fair Value</u>
Unvested balance as of December 31, 2025	26,417	\$ -
Vested	(5,414)	-
Unvested balance as of June 30, 2026	<u>21,003</u>	<u>\$ -</u>

Stock Option Awards

During the six months ended June 30, 2026, the Company granted an aggregate of 6,434 stock options to three non-employees under the Company’s 2025 Plan. The stock options have an exercise price of \$0.0001 per share and expire on February 10, 2036. The stock options are subject to service-based vesting requirements over approximately four years. For this six months ended June 30, 2026, stock-based compensation expense related to the Company’s outstanding stock options was deemed to be immaterial.

6. Income Taxes

The Company recorded no provision or benefit for income taxes for the six months ended June 30, 2026 and 2025. The Company’s estimated annual effective tax rate for 2026 is 0%. The Company expects a pre-tax loss for the year ending December 31, 2026 and maintains a full valuation allowance against its net deferred tax assets, which consist primarily of net operating loss carryforwards. The income tax benefit that would otherwise result from the pre-tax loss is fully offset by an increase in the valuation allowance, as the Company has concluded it is more likely than not that the deferred tax assets will not be realized.

7. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may become involved in legal proceedings or other litigation relating to claims arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and estimated exposure amount. Legal fees and other costs associated with such proceedings are expensed as incurred. As of June 30, 2026 and December 31, 2025, the Company was not a party to any material legal proceedings or claims.

VIDYA THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with each of its directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or executive officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of June 30, 2026.

8. Related Party Transactions

The Company entered into significant related party transactions during the six months ended June 30, 2025 related to the issuance of SAFEs (see Note 3). During the six months ended June 30, 2025, the Company issued SAFEs to related parties, including an entity affiliated with a member of the Company's Board of Directors, totaling \$2.1 million. The terms and conditions of the SAFEs issued to related parties were the same as those of the SAFEs issued to third-party investors during the respective periods. The Company did not have any significant related party transactions during the periods presented.

9. Subsequent Events

The Company has evaluated events and transactions occurring subsequent to June 30, 2026 through October 2, 2026, the date at which the condensed consolidated financial statements are available to be issued.

Merger Agreement

On July 28, 2026, the Company completed the transactions contemplated by the Agreement and Plan of Merger (the "Merger Agreement") with Processa and Venus Merger Sub I, Inc. and Venus Merger Sub II, LLC, both wholly owned subsidiaries of Processa. Pursuant to the Merger Agreement, Venus Merger Sub I, Inc. merged with and into Vidya, with Vidya continuing as a wholly owned subsidiary of Processa and the surviving corporation (the "First Merger"). Immediately following the First Merger and as part of the same overall transaction, Vidya merged with and into Venus Merger Sub II, LLC (the "Second Merger" and, together with the First Merger, the "Merger"), with Venus Merger Sub II, LLC being the surviving entity of the Second Merger.

Pursuant to the Merger Agreement, holders of Vidya equity securities, including all unvested RSAs and outstanding SAFEs, received an aggregate of 142,254.972 shares of Series A Preferred Stock. Outstanding Company options were assumed or exchanged for corresponding options to purchase an aggregate of 1,047,524 shares of Processa common stock.

Concurrent with the closing of the Merger, Processa completed a private placement financing with certain investors that generated gross proceeds of approximately \$200.0 million through the issuance of Series A Preferred Stock.

Receipt of Australian Research and Development Tax Incentive Refund

On September 17, 2026, Vidya Therapeutics Australia Pty. Ltd., the Company's wholly owned Australian subsidiary, received a cash refund of approximately \$1.7 million from the Australian Taxation Office related to the Australian RDTI claim for the income tax year ended June 30, 2026.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

Introduction

On July 28, 2026, Processa Pharmaceuticals, Inc. (“Processa” or the “Company”) acquired Vidya Therapeutics, Inc. (“Vidya”) pursuant to an Agreement and Plan of Merger (the “Merger Agreement”), dated as of July 28, 2026, by and among the Company, Venus Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company (“Merger Sub I”), Venus Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company (“Merger Sub II”), and Vidya, a Delaware corporation. Also, on July 28, 2026, the transactions contemplated by the Merger Agreement were consummated, pursuant to which Merger Sub I merged with and into Vidya, with Vidya surviving and becoming a wholly owned subsidiary of the Company (the “First Merger”). Immediately following the First Merger, Vidya merged with and into Merger Sub II, with Merger Sub II surviving as a wholly owned subsidiary of the Company and subsequently being renamed Vidya Therapeutics Operating LLC (together with the First Merger, the “Merger”). The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

Under the terms of the Merger Agreement, the Company issued to the stockholders of Vidya an aggregate of 142,254,972 shares of Series A Non-Voting Convertible Preferred Stock, par value \$0.0001 per share (the “Series A Preferred Stock”), which is inclusive of 37,518,329 shares of Series A Preferred Stock issued for the conversion of previously outstanding Simple Agreements for Future Equity (“SAFE’s”) issued by Vidya. Each share of Series A Preferred Stock is convertible into 1,000 shares of common stock of the Company, par value \$0.00001 per share (“Common Stock”), subject to receiving approval by the Company’s stockholders of the issuance of shares of Common Stock upon conversion of Series A Preferred Stock and exercise of certain options held by the former equity holders of Vidya that we assumed in the Merger, which (a) will represent more than 20% of the shares of Common Stock outstanding pursuant to Nasdaq Listing Rule 5635(a) and (b) may, together with certain changes to management and our Board of Directors (“Board”), result in a change of control of the Company pursuant to Nasdaq Listing Rule 5635(b) (the “Conversion Proposal”) and certain beneficial ownership limitations set by each holder. In addition, all outstanding options to purchase Vidya common stock were assumed by the Company and were converted into options to purchase an aggregate of 1,047,524 shares of Common Stock (the “Assumed Options”).

Concurrently with the Merger, on July 28, 2026, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with investors (the “PIPE Investors”) to raise \$200.0 million of gross proceeds in which the PIPE Investors were issued an aggregate of 163,774,679 shares of Series A Preferred Stock, or 163,774,679 on an as-converted-to-common basis and without giving effect to any beneficial ownership limitations, (the “PIPE Securities”) at a price of \$1,221.19 per share, or \$1.22 per share on an as-converted-to-common basis, (collectively, the “Financing”). The Financing closed on July 30, 2026.

As a result of the transactions, equityholders of the Company immediately prior to the Merger owned approximately 1.4% of the Common Stock, equityholders of Vidya immediately prior to the Merger owned approximately 46.0% of the Common Stock and investors in the Financing owned approximately 52.6% of the Common Stock, in each case, calculated on a fully-diluted, as-converted-to-common basis (and without giving effect to any beneficial ownership limitations) and based on the implied equity values of the Company and Vidya.

Unaudited Pro Forma Condensed Combined Financial Information

The unaudited pro forma condensed combined financial information is provided for illustrative purposes only, does not necessarily reflect what the actual consolidated results of operations and financial position would have been had the Merger occurred on the dates assumed and may not be useful in predicting the future consolidated results of operations or financial position. The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may result from the Merger.

The unaudited pro forma condensed combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. Accordingly, the pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed and have been made solely for the purpose of providing unaudited pro forma condensed combined financial information. Differences between the preliminary accounting and estimates reflected in the unaudited pro forma condensed combined financial information and the final accounting and estimates may occur and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information and the combined Company’s future results of operations and financial position.

Accounting rules require evaluation of certain assumptions, estimates, or determination of financial statement classifications. During preparation of the unaudited pro forma condensed combined financial information, management has performed a preliminary analysis and is not aware of any material differences, and accordingly, this unaudited pro forma condensed combined financial information assumes no material differences in accounting policies of the two companies. Following the Merger, management will conduct a final review of the Company’s accounting policies in order to determine if differences in accounting policies require adjustment or reclassification of Vidya’s results of operations or reclassification of assets or liabilities to conform to the Company’s accounting policies and classifications. As a result of this review, management may identify differences that, when conformed, could have a material impact on these unaudited pro forma condensed combined financial statements.

The following unaudited pro forma condensed combined financial information has been prepared in accordance with Article 11 of Regulation S-X under the Securities Act of 1933, as amended (the “Securities Act”) and presents the combined historical consolidated financial position and consolidated results of operations of the Company and the historical combined financial position and results of operations of Vidya, adjusted to give effect to (i) the Merger and the Financing and (ii) the pro forma effects of certain assumptions and adjustments described in “Notes to the Unaudited Pro Forma Condensed Combined Financial Information” below. Collectively, pro forma balance sheet transaction accounting adjustments and pro forma statements of operations transaction accounting adjustments are referred to as “transaction accounting adjustments.”

The following unaudited pro forma combined financial information is presented to illustrate the estimated effects of the Merger and Financing, based on the historical financial statements and accounting records of the Company and Vidya after giving effect to the Merger and Financing and the related pro forma adjustments as described in the notes included below.

The unaudited pro forma combined statements of operations for the six months ended June 30, 2026 and for the year ended December 31, 2025 combine the historical statements of operations of the Company and Vidya, giving effect to the Merger and Financing as if they had occurred on January 1, 2025. The unaudited pro forma condensed combined balance sheet data assumes that the Acquisition and Financing took place on June 30, 2026, and combines the historical balance sheets of the Company and Vidya as of such date.

The following unaudited pro forma condensed combined financial information and related notes are based on and should be read in conjunction with the following:

- (i) The accompanying notes to the unaudited pro forma condensed combined financial statements.
 - (ii) The historical unaudited financial statements of the Company and the related notes included in its Quarterly Report on Form 10-Q as of and for the three and six months ended June 30, 2026 filed with the Securities Exchange Commission (“SEC”) on August 14, 2026;
 - (iii) The historical audited financial statements of the Company and the related notes included in its Annual Report on Form 10-K as of and for the year ended December 31, 2025 filed with the SEC on March 18, 2026;
 - (iv) The historical unaudited financial statements of Vidya and the related notes as of and for the six months ended June 30, 2026 included in this Form 8-K/A filed with the SEC on October 5, 2026;
 - (v) The historical audited financial statements of Vidya and the related notes as of and for the year ended December 31, 2025 included in this Form 8-K/A filed with the SEC on October 5, 2026;
 - (vi) The Current Report on Form 8-K/A of the Company to which these unaudited pro forma condensed combined financial statements are attached as an exhibit.
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UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET
AS OF JUNE 30, 2026
(in thousands)

	Historical		Transaction Accounting Adjustments	Pro Forma Combined
	Processa	Vidya		
Assets				
Current assets:				
Cash and cash equivalents	\$ 196	\$ 245	\$ 183,725	A \$ 184,166
Digital assets at fair value	472	-	-	472
Prepaid expenses and other current assets	1,398	486	-	1,884
Total current assets	2,066	731	183,725	186,522
Property and equipment, net	3	-	-	3
Total assets	\$ 2,069	\$ 731	\$ 183,725	\$ 186,525
Liabilities, Convertible Preferred Stock, and Stockholders' Equity (Deficit)				
Current liabilities:				
Accounts payable	\$ 1,659	\$ 941	\$ -	\$ 2,600
SAFE liabilities, current	-	36,330	(36,330)	B -
Accrued expenses and other current liabilities	727	106	-	833
Total liabilities	2,386	37,377	(36,330)	3,433
Commitments and contingencies				
Processa convertible preferred stock	-	-	361,404	B 361,404
Stockholders' equity (deficit):				
Processa common stock	-	-	-	-
Vidya common stock	-	-	-	C -
Additional paid-in capital	107,108	3	1,277	C 108,388
Accumulated other comprehensive income	-	(20)	20	C -
Accumulated deficit	(107,425)	(36,629)	(142,646)	C (286,700)
Total stockholders' equity (deficit)	(317)	(36,646)	(141,349)	(178,312)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 2,069	\$ 731	\$ 183,725	\$ 186,525

See accompanying notes to the unaudited pro forma condensed combined financial information.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS

FOR THE SIX MONTHS ENDED JUNE 30, 2026

(in thousands of dollars, except shares and per share amounts)

	Historical		Transaction Accounting Adjustments	Pro Forma Combined
	Processa	Vidya		
Operating expenses:				
Research and development	\$ 2,459	\$ 2,178	\$ -	\$ 4,637
General and administrative	3,208	628	-	3,836
Total operating expenses	<u>5,667</u>	<u>2,806</u>	<u>-</u>	<u>8,473</u>
Loss from operations	<u>\$ (5,667)</u>	<u>\$ (2,806)</u>	<u>\$ -</u>	<u>\$ (8,473)</u>
Other income (expense), net:				
Unrealized loss on digital assets	(828)	-	-	(828)
Realized loss on digital assets	(159)	-	-	(159)
Interest income	12	16	-	28
Change in fair value of SAFE liability	-	(27,327)	27,327	G -
Total other (expense), net	<u>(975)</u>	<u>(27,311)</u>	<u>27,327</u>	<u>(959)</u>
Net loss	<u>\$ (6,642)</u>	<u>\$ (30,117)</u>	<u>\$ 27,327</u>	<u>\$ (9,432)</u>
Foreign currency translation adjustment	-	40	-	40
Total comprehensive loss	<u>\$ (6,642)</u>	<u>\$ (30,077)</u>	<u>\$ 27,327</u>	<u>\$ (9,392)</u>
Net loss attributable to common stockholders	<u>\$ (6,642)</u>	<u>\$ (30,117)</u>	<u>\$ 27,327</u>	<u>\$ (9,432)</u>
Net loss per share attributable to common stockholders — basic and diluted	<u>\$ (2.47)</u>			<u>\$ (3.51)</u>
Weighted average common shares outstanding — basic and diluted ⁽¹⁾	<u>2,687,295</u>			<u>2,687,295</u>

⁽¹⁾ Reflects the exclusion of the shares of Common Stock issuable upon conversion of the Series A Preferred Stock from diluted weighted-average common shares outstanding as their inclusion would be anti-dilutive for the periods presented. The Series A Preferred Stock is a participating security, however, because holders are not contractually obligated to participate in losses, no loss has been allocated to the Series A Preferred Stock under the two-class method.

See accompanying notes to the unaudited pro forma condensed combined financial information.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS
FOR THE YEAR ENDED DECEMBER 31, 2025

(in thousands of dollars, except shares and per share amounts)

	Historical		Transaction		Pro Forma
	Processa	Vidya	Accounting		Combined
			Adjustments		
Operating expenses:					
Research and development	\$ 7,810	\$ 2,818	326	D	\$ 10,954
General and administrative	6,178	487	2,275	A	9,033
			93	E	
Acquired in-process research and development	-	-	2,000	A	177,000
			175,000	F	
Total operating expenses	13,988	3,305	179,694		196,987
Loss from operations	\$ (13,988)	\$ (3,305)	\$ (179,694)		\$ (196,987)
Other income (expense), net:					
Interest income	109	136	-		245
Unrealized gain on digital assets at fair value	295	-	-		295
Change in fair value of SAFE liability	-	(2,892)	2,892	G	-
Other income	20	-	-		20
Total other income (expense), net	424	(2,756)	2,892		560
Net loss	\$ (13,564)	\$ (6,061)	\$ (176,802)		\$ (196,427)
Foreign currency translation adjustment	-	(60)	-		(60)
Total comprehensive loss	\$ (13,564)	\$ (6,121)	\$ (176,802)		\$ (196,487)
Net loss attributable to common stockholders	\$ (13,564)	\$ (6,061)	\$ (176,802)		\$ (196,427)
Net loss per share attributable to common stockholders — basic and diluted	\$ (10.36)				\$ (150.03)
Weighted average common shares outstanding — basic and diluted ⁽¹⁾	1,309,271				1,309,271

⁽¹⁾ Reflects the exclusion of the shares of Common Stock issuable upon conversion of the Series A Preferred Stock from diluted weighted-average common shares outstanding as their inclusion would be anti-dilutive for the periods presented. The Series A Preferred Stock is a participating security, however, because holders are not contractually obligated to participate in losses, no loss has been allocated to the Series A Preferred Stock under the two-class method.

See accompanying notes to the unaudited pro forma condensed combined financial information.

NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

Note 1. Basis of presentation

Description of the Transactions

On July 28, 2026, the Company acquired Vidya through the Merger. Upon consummation of the Merger, all outstanding options to purchase Vidya common stock were assumed by the Company and were converted into options to purchase an aggregate of 1,047,524 shares of Common Stock. Additionally, the Company issued 142,254,972 shares of Series A Preferred Stock, which is inclusive of 37,518,329 shares of Series A Preferred Stock issued for the conversion of previously outstanding Vidya SAFE's. Each share of which is convertible into 1,000 shares of Common Stock, subject to stockholder approval of the Conversion Proposal and beneficial ownership limitations set by each holder.

On July 28, 2026, the Company entered into the Purchase Agreement with PIPE investors, pursuant to which the Company agreed to sell an aggregate of 163,774,679 shares of Series A Preferred Stock for an aggregate cash purchase price of approximately \$200.0 million. Each share of Series A Preferred Stock is convertible into 1,000 shares of Common Stock, subject to stockholder approval of the Conversion Proposal and certain beneficial ownership limitations set by each holder. The closing of the Financing occurred on July 30, 2026.

Pursuant to the Merger Agreement, the Company has agreed to hold a stockholders' meeting to submit certain matters to its stockholders for consideration, including (i) the issuance of shares of Common Stock upon conversion of the Series A Preferred Stock issued in connection with the Merger and exercise of certain Assumed Options pursuant to Nasdaq Listing Rules 5635(a) and 5635(b), (ii) the issuance of shares of Common Stock upon conversion of the Series A Preferred Stock issued in connection with the Financing pursuant to Nasdaq Listing Rule 5635(d), (iii) approval of the 2026 Equity Incentive Plan, and (iv) approval of the 2026 Employee Stock Purchase Plan.

Basis of Presentation

The unaudited pro forma condensed combined financial information was preliminarily prepared with the Merger being accounted for as an asset acquisition with the Company as the accounting acquirer. Upon completion of the Merger and Financing, the Company obtained control of Vidya's assets, consisting primarily of in-process research and development ("IPR&D"). In accordance with Accounting Standards Codification Topic 805, Business Combinations ("ASC 805"), under the asset acquisition method of accounting, the assets acquired and liabilities assumed are recognized and measured at fair value and no goodwill is recorded or recognized. Acquired IPR&D that has no future alternative use is expensed at the time of acquisition.

The unaudited pro forma condensed combined financial statements have been prepared based on the Company's and Vidya's historical financial information, giving effect to the Merger and related adjustments described in these notes to show how the Merger might have affected the historical financial statements if it had been completed on January 1, 2025 for the purposes of the unaudited pro forma condensed combined statements of operations for the six months ended June 30, 2026 and for the year ended December 31, 2025; and as of June 30, 2026, for purposes of the unaudited pro forma condensed combined balance sheet.

The pro forma adjustments reflecting the consummation of the Merger and the Financing are based on certain currently available information and certain assumptions and methodologies that the Company believes are reasonable under the circumstances. The pro forma adjustments, which are described in the accompanying notes, may be revised as additional information becomes available and is evaluated. Therefore, it is likely that the actual adjustments will differ from the pro forma adjustments, and it is possible the difference may be material. The Company believes that its assumptions and methodologies provide a reasonable basis for presenting all of the significant effects of the Merger based on information available to management at this time and that the pro forma adjustments give appropriate effect to those assumptions and are properly applied in the unaudited pro forma condensed combined financial information.

The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, anticipated synergies, operating efficiencies, tax savings, or other savings or expenses that may be associated with the integration of the two companies and does not purport to represent the actual results of operations that the Company and Vidya would have achieved had the companies been combined during the periods presented and is not intended to project the future results of operations that the combined company may achieve after the Merger.

Note 2. Estimated consideration and preliminary purchase price allocation

The estimated fair value of the consideration transferred of \$175.0 million is summarized as follows (in thousands):

Assumed Options ⁽¹⁾	\$ 1,280
Series A Preferred Stock ⁽²⁾	173,720
Total consideration transferred	<u>\$ 175,000</u>

⁽¹⁾ Reflects the portion of the acquisition date fair-value based measure of the Assumed Options

⁽²⁾ The fair value of the consideration transferred was measured using the price per share the investors paid as part of the Financing

The net liabilities acquired in connection with the Merger were determined to be immaterial. Accordingly, for purposes of the pro forma financial statements, the purchase consideration of \$175.0 million was fully allocated to the acquired IPR&D.

Note 3. Transaction accounting adjustments

Adjustments included in the column under the heading “Transaction Accounting Adjustments” are primarily based on information contained within the Merger Agreement. Further analysis will be performed after the completion of the Merger to confirm these estimates or make adjustments in the final purchase price allocation, as necessary. The transaction adjustments included in the unaudited pro forma condensed combined financial statements are as follows:

- A. Reflects the receipt of \$200.0 million of gross proceeds from the Financing and the payment of \$16.3 million of transaction-related costs at closing, consisting of \$12.0 million of placement agent fees, \$2.0 million of merger transaction success fee and \$2.3 million of other transaction and SEC reporting costs, resulting in a net increase in cash of \$183.7 million. The \$12.0 million of placement agent fees are reflected as a reduction of the carrying amount of the Series A Preferred Stock issued in the Financing. The remaining transaction costs are accounted for separately as described below.

Gross proceeds from financing	\$ 200,000
Placement agent fees	(12,000)
Merger transaction fee	(2,000)
Other transaction and SEC reporting costs	(2,275)
Pro forma adjustment	<u>\$ 183,725</u>

- B. Reflects the recording of the (i) issuance of 142,254.972 of the Company’s shares of Series A Preferred Stock to Vidya stockholders, which is inclusive of 37,518.329 shares of Series A Preferred Stock issued for the conversion of \$36.3 million of previously outstanding Vidya SAFE’s, and (ii) issuance of 163,774.68 of the Company’s shares of Series A Preferred Stock as a result of the Financing, which is reflected at \$188.0 million, representing gross proceeds of \$200.0 million, net of \$12.0 million of placement agent fees directly attributable to the Financing (in thousands, except share amounts):

	Series A Preferred Stock	
	Shares	Amount
Issuance of Series A Preferred Stock to Vidya’s stockholders	142,254.97	\$ 173,404
Issuance of Series A Preferred Stock related to the Financing	163,774.68	188,000
Pro forma adjustment	<u>306,029.65</u>	<u>\$ 361,404</u>

- C. Reflects the recording of the (i) elimination of Vidya’s historical equity balances, (ii) exchange of Vidya stock options for the Assumed Options, which is reflected as consideration, (iii) the immediate expensing of the Merger transaction fee incurred upon consummation of the Merger, (iv) the immediate expensing of Vidya’s merger related transaction expenses, and (v) the immediate expensing of acquired Vidya IPR&D as it has no future alternative use (in thousands, except share amounts):

	Common Stock		Additional paid-in-capital	Accumulated other comprehensive income	Accumulated Deficit	Total
	Shares	Amount				
Elimination of Vidya’s historical equity balances as of June 30, 2026	(643,302)	\$ -	\$ (3)	\$ 20	\$ 36,629	\$ 36,646
Exchange of Vidya options for stock options of the Company	-	-	1,280	-	-	1,280
Expensing of Merger transaction fee	-	-	-	-	(2,000)	(2,000)
Expensing of Vidya transaction costs	-	-	-	-	(2,275)	(2,275)
Expensing of Acquired IPR&D	-	-	-	-	(175,000)	(175,000)
Pro forma adjustment	<u>(643,302)</u>	<u>\$ -</u>	<u>\$ 1,277</u>	<u>\$ 20</u>	<u>\$ (142,646)</u>	<u>\$ (141,349)</u>

- D.** Represents compensation-related costs associated with the Merger that are reflected within research and development expense, summarized as follows (in thousands):

Compensation expense for Assumed Options attributable to post-combination services ⁽¹⁾	\$ 326
Pro forma adjustment	<u>\$ 326</u>

⁽¹⁾ Pro forma compensation expense for the Assumed Options has been calculated using the acquisition-date fair value of the Assumed Options.

- E.** Represents compensation-related costs associated with the Merger that are reflected within general and administrative expense, summarized as follows (in thousands):

Compensation expense for Assumed Options attributable to post-combination services ⁽¹⁾	\$ 93
Pro forma adjustment	<u>\$ 93</u>

⁽¹⁾ Pro forma compensation expense for the Assumed Options has been calculated using the acquisition-date fair value of the Assumed Options.

- F.** Reflects the recognition of \$175.0 million of in-process research and development expense related to the acquired programs that had no alternative future use at the time of Merger which requires immediate expense recognition.
- G.** To reflect Vidya's change in fair value related to its SAFE instruments that is recorded in its historical financial statements, to be derecognized in the unaudited pro forma condensed combined statement of operations for the twelve months ended December 31, 2025 and six months ended June 30, 2026, assuming the adjustment described in Note B was made on January 1, 2025.
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