

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

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2025  
or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the transition period from to

Commission File Number 001-39527

**PRELUDE THERAPEUTICS INCORPORATED**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**175 Innovation Boulevard**  
**Wilmington, Delaware**  
(Address of principal executive offices)

**81-1384762**  
(I.R.S. Employer  
Identification No.)

**19805**  
(Zip Code)

Registrant's telephone number, including area code: (302) 467-1280

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	PRLD	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES  NO

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES  NO

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES  NO

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES  NO

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b).

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  NO

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$14.4 million as of the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing sale price on The Nasdaq Global Select Market reported for such date.

The number of shares of registrant's Common Stock outstanding as of March 6, 2026 was 63,002,248.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement ("Proxy Statement") relating to the 2026 Annual Meeting of Stockholders will be filed with the Commission within 120 days after the end of the Registrant's 2025 fiscal year pursuant to Regulation 14A and is incorporated by reference into Part III of this Report. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

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## PART I

*This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions, including those relating to future events or our future financial performance. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," "schedule," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are predictions based on the Company's current expectations and projections about future events and various assumptions. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading "Item 1A—Risk Factors." It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report on Form 10-K may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.*

### Item 1. Business.

#### Overview

Prelude Therapeutics Incorporated ("Prelude" or the "Company") is a precision oncology company built on a foundation of drug discovery excellence to deliver novel precision cancer medicines to underserved patients. By leveraging our core competencies in cancer biology and medicinal chemistry, combined with our clinical development capabilities, we have built an efficient, drug discovery engine and the development expertise necessary to identify compelling biological targets and create new chemical entities, or NCEs, that we advance into clinical trials. We believe our approach could result in better targeted cancer therapies. Our discovery excellence has been supported by our steady progress in advancing a pipeline of novel precision oncology development candidates, alone and with partners. We are working with our partner AbCellera Biologics, Inc. ("AbCellera") on an early-stage discovery program involving potent degraders as payloads for novel antibodies targeting tumor specific antigens. Since our inception in 2016, we have received clearance from the U.S. Food and Drug Administration, or the FDA, for multiple investigational new drug applications, or INDs, and successfully advanced several programs into clinical trials. In addition, we have other differentiated proprietary programs in various stages of preclinical development.

By focusing on developing molecules using broad mechanisms that have multiple links to oncogenic driver pathways in select patients, we have developed a diverse pipeline consisting of multiple distinct programs including kinases, targeted protein degraders, and precision antibody drug conjugates. Our pipeline is designed to serve patients with high unmet medical need, where there are limited or no treatment options. We believe we can best address these diseases by harnessing advances in new therapeutic modalities such as targeted protein degradation to develop highly potent and specific agents against clinically validated targets in areas of high unmet need.

The following table summarizes our product candidate pipeline:

PROGRAM	POTENTIAL INDICATIONS	DISCOVERY/ LEAD OPT.	IND-ENABLING	PHASE 1	PROGRAM INTEREST	MILESTONES
<b>JAK2V617F Mutant Selective JH2 Inhibitors</b>	VF+ myeloproliferative neoplasms (MPNs) (MF, PV, ET)		PRT12396		<sup>1</sup>	Phase 1 initiation anticipated in 2Q 2026
<b>KAT6A Selective Degraders</b>	ER+ breast cancer, other malignancies		PRT13722		Prelude wholly owned	IND filing mid-2026
<b>mCALR DAC</b>	CALR-mutated MPNs (ET, MF)				Prelude wholly owned	Oral abstract presented at ASH 2025
<b>Degrader Payloads for DACs</b>	Broad utility across multiple indications		<i>Proprietary degrader payloads available for licensing to partners developing next generation DACs</i>		<sup>2</sup>	Additional Partnerships

JAK2, janus kinase 2; JH2, JAK2 homology domain 2 (pseudokinase regulatory domain); VF+, V617F mutated; MPNs, myeloproliferative neoplasms; MF, myelofibrosis; PV, polycythemia vera; ET, essential thrombocythemia; ER+, estrogen receptor positive; DAC, degrader antibody conjugate; mCALR = mutated calreticulin  
 1 - Exclusive option agreement with Incyte (Nov. 2025)  
 2 - DAC Discovery Collaboration with AbCellera (Nov. 2023, amended and expanded 2H 2025)



## Prelude Discovery and Development Approach

We carefully evaluate and select our targets based on three key pillars, which provide a framework for optimizing our drug discovery and development efforts.

- Identify target mechanisms with a compelling biological rationale
  - o *Current target mechanisms of focus include transcriptional regulation and uncontrolled cell proliferation signaling mediated by well characterized driver mutations.*
- Leverage our advanced medicinal chemistry capabilities to create better product candidates
  - o *We leverage multiple modalities (inhibitors, degraders, and antibody-drug conjugates) in order to deliver clinical candidates that meet our desired target product profiles. Clinical candidates from all programs to-date have been internally designed and developed.*
- Pursue targets that drive cancers with high unmet need
  - o *Focus on targets that allow us to select patients and cancers with high unmet need with no approved therapies, or patient populations that are underserved by approved treatments.*

Once we have identified optimal targets using the three pillars above, we engage our unique discovery engine to invent and develop molecules rapidly and efficiently. We believe our expertise, capabilities and experience to select potentially high value biological targets and invent molecules with an optimized balance of biological and chemical properties differentiates us from others in the precision oncology space.

We design our clinical trials to leverage the potential broad utility of our compounds with a focus on efficient regulatory pathways to enable our potentially transformative medicines, aiming to quickly reach patients with high unmet medical need. By focusing on what we believe are clinically validated targets with a clear path to differentiation and early clinical proof-of-concept, we seek to advance our programs through expedited approval processes, as available. We believe that we can generate proof-of-concept clinical data to guide our future regulatory pathways to approval.

## Our Strategy

We aim to create better targeted and more effective cancer therapies. Our goal is to transform the lives of patients with cancer by leveraging the core competencies of our experienced team in medicinal chemistry, cancer biology and clinical

development to bring novel drugs to market. We intend to become a fully integrated oncology company on the foundation of drug discovery excellence to deliver novel precision oncology medicines to patients with underserved cancers by pursuing the following objectives:

- Leverage our cancer biology and medicinal chemistry expertise
- Discover and develop first or best-in-class differentiated development candidates that address unmet needs of oncology patients.
- Rapidly progress our product candidates through clinical development in patients with solid tumors and hematological malignancies.
- Focus clinical development on underserved cancers and design clinical trials that allow for efficient decision-making with the highest probability of success and potential for rapid regulatory approval.
- Advance our product candidate pipeline in combination with internally discovered and third-party developed compounds.
- Evaluate strategic opportunities to accelerate development timelines and maximize the value of our product candidates.

## **Our Product Candidates**

### **JAK2V617F**

#### ***Background***

JAK2V617F is the primary driver mutation responsible for disease progression in the majority of patients living with myeloproliferative neoplasms (MPNs). The mutation impacts approximately 95% of patients with polycythemia vera (PV), 60% of patients with essential thrombocythemia (ET) and 55% of patients with myelofibrosis (MF). Identifying JAK2 JH2 inhibitors that selectively target V617F+ cells has long been a shared goal and challenge for industry. If successful, this approach has potential to reduce mutant allele burden, modify disease progression, and transform treatment outcomes for MPN patients.

#### ***Our JAK2V617F Program***

We have designed and identified novel allosteric inhibitors that bind into the JAK2 JH2 “deep pocket” where the V617F mutation resides. These candidates demonstrate mutant specific inhibition in multiple preclinical models of MPNs. We believe this approach may have the potential to reduce mutant allele burden, slow or even reverse disease progression, and transform treatment outcomes for MPN patients.

PRT12396, our lead, mutant-selective JAK2V617F inhibitor received IND clearance from the U.S. FDA, as announced in February 2026 and we anticipate initiating a Phase 1 study in the second quarter of 2026.

This program is the subject of an Exclusive Option Agreement (the “Option Agreement”) with Incyte Corporation (“Incyte”) as announced on November 4, 2025. Under the Option Agreement, Incyte received an exclusive option to acquire our entire right, title, and interest in and to certain assets, properties, and rights related to the Program, including our library of preclinical candidates (collectively, the “Transferred Assets”).

The Option Agreement included, as an exhibit, the form of an Asset Purchase Agreement (the “APA”), which contemplates the sale, transfer, assignment, and conveyance by us to Incyte, and the purchase, acquisition, and assumption by Incyte from us, of the our entire right, title, and interest in and to the Transferred Assets in the event Incyte exercises its option under the Option Agreement.

At any time commencing on the effective date of the Option Agreement until a maximum of 18 months from the effective date (the “Option Period”), Incyte may elect to exercise its exclusive option to acquire the Program and associated assets from us pursuant to the APA for \$100 million. We are continuing to advance the Program during the Option Period. We received \$60 million in capital upon signing the Option Agreement, comprised of an initial payment of \$35 million in cash, plus a \$25 million equity investment by Incyte. Under the APA, we would be eligible to receive up to \$775 million in additional clinical and regulatory milestones, and single digit royalties on global net sales. Combined, total potential cash payments from the transaction could reach up to \$910 million.

We continue to own and develop all program assets during the Option Period. If the option is exercised during the Option Period and the parties enter into and close the transaction set forth in the APA, Incyte will own all Transferred Assets subject to our right, in our sole discretion and cost, to continue to conduct development activities during the Option Period to nominate and select additional development candidate(s) for the Program. If Incyte elects to not exercise its option to acquire the Program or close the transaction, all JAK2 V617F program assets would remain in our sole ownership and control.

## **KAT6A**

### ***Background***

There is a high unmet need for novel modalities to treat advanced breast cancer & other solid tumors. KAT6A and KAT6B are part of the 8p11 amplicon and histone acetyltransferase (HAT) complex which regulates the expression of a number of genes involved in regulating cancer cell growth and survival, including the estrogen receptor (ER), progesterone receptor (PR) and MYC. KAT6A amplification and overexpression in cancer leads to increased activity and because KAT6A regulates the expression of ER, MYC and other cell cycle genes, its increased activity drives ER+ BC growth. Although KAT6A overexpression drives cancer growth, both KAT6A and its related family member KAT6B are important in normal hematopoiesis and preclinical data demonstrate that loss of both KAT6A and B results in bone marrow toxicity.

### ***Our KAT6 Selective Degradation Program***

Our approach of selectively degrading KAT6A has the potential to deliver differentiated safety and efficacy over non-selective KAT6A/B inhibitors. Our preclinical data demonstrate that selective KAT6A degradation shows robust efficacy in ER+ BC models. Our lead KAT6A degrader is a highly potent degrader of KAT6A with selectivity for KAT6A over KAT6B of greater than 1000 fold. We have observed oral PK across all species, and *in vivo* efficacy as monotherapy with complete regressions observed at well-tolerated, low once daily oral doses in preclinical models of KAT6A amplified and non-amplified ER+ BC.

We have selected a development candidate and remain on track to file an IND in mid-2026 with Phase 1 study initiation anticipated in the second half of 2026.

## **Other Discovery Programs**

As mentioned above, our goal is to transform the lives of patients with cancer by leveraging the core competencies of our experienced team in medicinal chemistry, cancer biology and clinical development to bring novel drugs to market. As such, our discovery programs include the following:

### ***Mutated Calreticulin (mCALR) degrader antibody conjugates (DACs)***

Mutant CALR is a neoantigen presented on the cell surface of malignant myeloid cells but not normal cells and is found in approximately 25-35% of patients with myelofibrosis (MF) and essential thrombocythemia (ET). Current therapies for MPNs provide symptom relief but do not reduce allele burden, and are not curative and identification of therapeutic approaches that can selectively eliminate mutant CALR disease-initiating progenitors is an unmet medical need. Recently, an mCALR-targeted monoclonal antibody demonstrated robust clinical activity in high-risk ET patients. We are seeking to further optimize this modality by developing mCALR-targeted DACs using our proprietary degrader payloads.

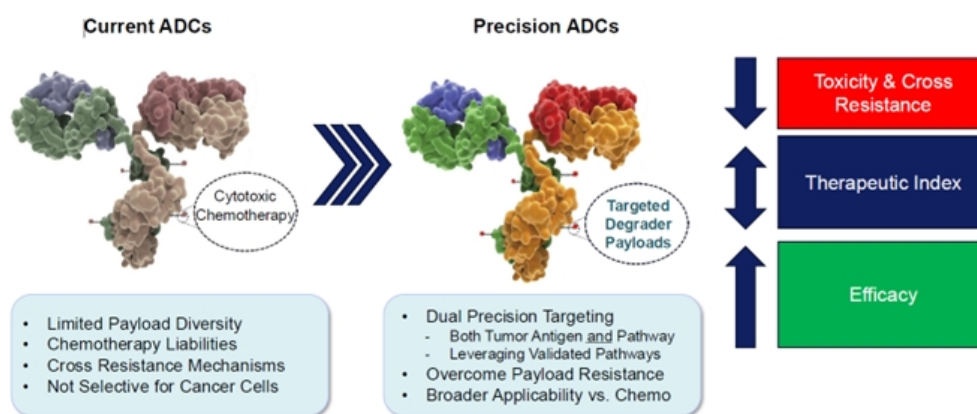
SMARCA2/4 and CDK9 degraders are both highly active in CALR mutated MPN cell lines and can be used as payloads for mCALR-targeted DACs. mCALR-targeted DACs, delivering our degrader payloads to disease-initiating clones have the potential to be first-in-class, disease modifying therapies.

### ***Precision Antibody Drug Conjugates (ADCs)***

#### ***Background***

Among ADCs in the clinic, "Precision ADCs" with novel degrader payloads are only now emerging. Most "Next Gen" ADCs in the clinic are still using older cytotoxics as payloads, with similar liabilities and limited scope for diversification. Targeted protein degraders (TPD) are uniquely suited as payloads with exquisite potencies and added benefit of targeting precision biological pathway. Novel TPD payloads can be designed with properties to avoid exposure to healthy tissues such

as low cell penetration and high plasma clearance. Precision ADCs with degrader-prodrug payloads have the potential to confer both improved efficacy and improved tolerability.



In 2023, we entered into a multi-year, multi-program agreement with AbCellera Biologics Incorporated ("AbCellera") to jointly discover, develop, and commercialize novel degrader antibody conjugates ("DACs") for up to five programs (the "Collaboration Agreement"). We believe the Collaboration Agreement will allow us to combine our small molecules and degraders expertise with their antibody expertise to develop precision antibody drug conjugates. As one of our first precision ADC programs, we and our partner AbCellera began work on an early-stage discovery program involving potent degraders of the SMARCA family of proteins as payloads for novel antibodies targeting tumor specific antigens. Given the potent anti-tumor activity of these molecules in pre-clinical models of cancers, we believe that these precision ADCs have the potential to extend the therapeutic utility of this class. The partnership includes up to five precision ADC targets. Under the terms of the agreement, AbCellera will lead manufacturing activities and the Company will lead clinical development and global commercialization, subject to AbCellera's option to co-promote any resulting commercial products in the United States.

During the third quarter of 2025 we amended our collaboration with AbCellera (the "Amended Agreement") and, subsequently in October 2025, further expanded the collaboration (the "Expanded License Agreement"). The Amended Agreement and Expanded License Agreement provided AbCellera a non-exclusive license to use certain of our degrader payloads to independently discover, develop and commercialize a select number of DACs against undisclosed antibody targets. The agreements also entailed other changes to overall resource allocation and collaboration governance. For the newly licensed DAC programs, AbCellera received world-wide rights to lead and fully control the licensed programs at its sole cost and expense and we are not responsible for any additional financial responsibilities or go forward development costs associated with those programs. We received an upfront non-refundable payment from AbCellera of \$6.5 million in the third quarter of 2025 upon signing the Amended Agreement and an upfront non-refundable payment of \$6 million in October 2025 upon signing of the Expanded License Agreement. For the additional licensed DACs, we are also eligible to receive customary downstream milestones and single digit royalties on future product sales. The original Collaboration Agreement, whereunder the companies can jointly discover, develop, and commercialize novel DACs for up to five programs remains in effect.

Outside of the AbCellera collaboration, we have discovered and optimized a number of pre-clinical precision payloads. We disclosed first data about these precision payloads at the 36th EORTC-NCI-AACR Symposium describing preclinical proof-of-concept using a novel, potent SMARCA2/4 dual degrader as a "Precision Payload" conjugated to multiple antibodies. Our SMARCA2/4 dual degraders have shown picomolar potency with potential for increased efficacy, selectivity and improved therapeutic index across a wide range of cancer types.

With this experience, we have developed a degrader payload platform, designed and engineered to improve efficacy and tolerability, as compared to traditional cytotoxic payloads. Our potent and cell line selective targeted protein degraders are designed to be highly effective payloads. Payload permeability is maintained to provide an intact bystander effect for enhanced tumor kill. Prodrugs of the degrader payloads are engineered to have no membrane permeability to limit systemic toxicity. Payloads are engineered to have high clearance in vivo to help reduce systemic toxicity. In addition, highly stable degraders have the potential to provide improved efficacy. Accordingly, we believe that precision ADCs have the potential to deliver both improved efficacy and improved tolerability across several cancer types.

## **SMARCA2 (BRM) selective degrader program**

### ***Background***

SMARCA2, or BRM, and its related family member, SMARCA4, or BRG1, are the enzymatic subunits of the SWI/SNF complex that regulates gene expression by allowing the DNA to be accessible for transcription to mature RNA, a process known as chromatin remodeling. *SMARCA4* is mutated in multiple cancers, including 10-12% of NSCLC, resulting in loss of SMARCA4 protein. Because the activity of either SMARCA2 or SMARCA4 is required for chromatin remodeling to occur, the *SMARCA4*-deficient cancer cells become highly dependent on SMARCA2 for their survival. Therefore, we believe targeting SMARCA2 in *SMARCA4*-deficient cancers will produce a strong synthetic lethality, resulting in *SMARCA4* mutant tumor cell death while sparing normal cells that express SMARCA4 protein.

### ***Our SMARCA2 Selective Degradation Program***

A molecule capable of targeting a protein for degradation (degrader) typically contains a binding element to a targeted protein of interest (SMARCA2), a chemical linker and an E3 ligase binding element which allows for the formation of a ternary complex between the target, the degrader and the E3 ligase that induces ubiquitination and subsequent degradation of the targeted protein. Selectivity can be achieved, not only by the selective binding to the target (SMARCA2), but also through the optimization of the unique ternary complexes formed by the target (SMARCA2) versus its homologous protein (SMARCA4). PRT3789 is a first-in-class, highly selective degrader of SMARCA2 protein, which along with SMARCA4 controls gene regulation through chromatin remodeling. PRT7732 is >1000-fold selective for SMARCA2 vs. SMARCA4 and demonstrates robust activity in SMARCA4 deficient preclinical cancer models both as monotherapy and in combination with docetaxel at well-tolerated doses.

On November 4, 2025 we announced that we decided to pause the clinical development of our SMARCA2 degrader program which is comprised of PRT3789 and PRT7732 and prioritize allocation of resources to advancing the JAK2 V617F and KAT6A selective degrader programs.

### **Intellectual Property**

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the compositions of matter of our product candidates, their methods of use, related technology, and other inventions that are important to our business.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions, and know-how related to our business, to defend and enforce our patents, to preserve the confidentiality of our trade secrets, and to operate without infringing valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how and continuing technological innovation to develop, strengthen, and maintain our proprietary position in the field of precision oncology.

As more fully described below, our patent portfolio includes, inter alia, patent families with claims directed to compositions of matter for, and methods of using our compounds. The patent portfolio currently comprises of 282 patents and patent applications:

- (A)(i) 14 issued U.S. patents, (ii) 28 U.S. non-provisional patent applications, and (iii) 19 U.S. provisional patent applications; and
- (B)(iv) 21 PCT patent applications, (v) 59 issued foreign patents including patents in European jurisdictions, and (vi) 141 foreign patent applications.

As of the present filing, a total of 14 U.S. patents have been issued, which are wholly owned by us.

In addition to our filings in the U.S., we own patents and pending patent applications in Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, India, Israel, Japan, Mexico, New Zealand, South Africa, South Korea, and Ukraine.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In the countries in which we file, the patent term is 20 years from the earliest non-provisional filing date, subject to any disclaimers or extensions. The term of a patent in the United States can be adjusted due to any failure of the United States Patent and Trademark Office following certain statutory and regulation deadlines for issuing a patent.

In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for a portion of the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the original

expiration of the patent, subject to certain limits and calculations. The protection provided by a patent varies from country to country, and is dependent on the type of patent granted, the scope of the patent claims, and the legal remedies available in a given country.

Obtaining patent protection is not the only method that we employ to protect our proprietary rights. We also utilize other forms of intellectual property protection, including trademark, copyright, and trade secrets, when those other forms are better suited to protect a particular aspect of our intellectual property. Our belief is that our proprietary rights are strengthened by our comprehensive approach to intellectual property protection. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property.

### **Manufacturing**

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely for the foreseeable future, on third parties for the manufacture of our product candidates for preclinical and clinical testing, including pharmaceutical ingredients and clinical drug supply, as well as for commercial manufacture of any drugs that we may commercialize. We obtain our supplies from these manufacturers on a purchase order basis and do not have long-term supply arrangements in place. We do not own in-house warehouse facilities. We rely on third parties for storage and distribution of drug substance and drug product. We do not currently have arrangements in place for redundant supply for active pharmaceutical ingredients and drug product. As our development programs progress and we build new process efficiencies, we expect to continually evaluate this strategy with the objective of satisfying demand for registration trials and, if approved, the manufacture, sale and distribution of commercial products.

### **Commercialization**

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. If we are successful in obtaining the necessary regulatory approval, we may pursue commercialization on our own or seek to collaborate with a third party for commercialization, particularly outside the United States.

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, intense competition and a strong emphasis on intellectual property. We believe that our approach, strategy, scientific capabilities, know-how and experience provide us with competitive advantages. However, we expect substantial competition from multiple sources, including major pharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide. Many of our competitors, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

## Competition

We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of precision oncology therapies optimized to target the key driver mechanisms in cancers with high unmet need.

For our JAK2V617F inhibitor program, competition includes Ajax Therapeutics, Atavistik Bio, Cogent Biosciences, Eilean Therapeutics, Incyte Corporation, Llydlaw Therapeutics, Rathyra Therapeutics, and V6 Therapeutics. These companies have publicly disclosed their research and development efforts in this area.

For our KAT6A degrader program, other companies, including Pfizer, Olema Oncology, Menarini Group, BeOne Medicines (f/k/a BeiGene), Ideaya Biosciences, Isosterix, ProtAI, and Beijing Konruns Pharmaceutical have publicly disclosed their research and development efforts in this area.

More broadly, several global biopharmaceutical companies have prioritized precision oncology as an area of strategic focus, including but not limited to Amgen Inc., AbbVie Inc., AstraZeneca PLC, Astellas Inc., Bayer AG, Boehringer Ingelheim AG, Bristol Myers Squibb, Inc., Daiichi Sankyo Inc., Eli Lilly and Company, Inc., F. Hoffman-La Roche, Gilead Sciences Inc., GlaxoSmithKline PLC, Johnson & Johnson Services, Inc., Merck & Co. Inc., Novartis AG, and Pfizer Inc. In addition, there are multiple smaller biotech companies focused on discovery and development of precision oncology medicines, including but not limited to Arvinas Inc., Aurigene, Black Diamond Therapeutics, Inc., C4 Therapeutics, Foghorn Therapeutics Inc., Ideaya Biosciences, Kura Oncology, Inc., Kymera Therapeutics Inc., Nuvation Bio Inc., Repare Therapeutics Inc., Revolution Medicines, Inc., Relay Therapeutics, Inc., Tango Therapeutics, Inc., and Zentalis Pharmaceuticals, Inc.

We could see a reduction or elimination in our commercial opportunity if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive or with more favorable labeling than our product candidates. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

## Government Regulation

Government authorities in the U.S., at the federal, state and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

### *FDA Approval Process*

In the U.S., pharmaceutical products are subject to extensive regulation by the FDA, under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and other federal and state statutes and regulations governing, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending new drug applications, or NDAs, warning or untitled letters, inspectional findings product recalls, product seizures, import detention, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. We may also be debarred by the FDA, excluded, deemed to be ineligible, or debarred from government contracting, or excluded from participation in government healthcare programs. Regulatory requirements governing our business are evolving. FDA also continually issues guidance documents that provide FDA's interpretation of its laws and regulations, as well as FDA's approach to scientific issues and questions. For instance, with respect to cancer,

FDA has issued a number of guidances with respect to patient reported outcomes, clinical trial eligibility criteria, dose optimization, and multiregional clinical trials.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves preclinical laboratory and animal tests, the submission to FDA of an IND which must become effective before clinical testing in the U.S. may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including Good Laboratory Practice, or GLP, regulations and other applicable laws or regulations. In 2025, however, FDA announced a plan to reduce animal testing, with an initial focus on monoclonal antibodies. The results of preclinical testing are submitted to FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, a proposed clinical trial protocol, and any available clinical data or literature on the product candidate. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If FDA has not placed the study on clinical hold within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with Good Clinical Practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to FDA as part of the IND. Sponsors will also be required to provide FDA with diversity action plans once such requirements go into effect.

FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. Imposition of a clinical hold may be full or partial. The study protocol and informed consent information for patients in clinical trials must also be submitted for approval to an institutional review board, or IRB, and ethics committee for approval. An IRB considers among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits, and whether the planned human subject protections are adequate. The IRB will also monitor the clinical trial until completed. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Progress reports detailing the results of the clinical trials must be submitted at least annually to FDA and the IRB and more frequently if serious adverse events or other significant safety information is found. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial. Subjects participating in clinical trials must also provide their informed consent on the IRB approved form.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, mechanism of action, absorption, metabolism distribution, excretion, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. The FDA typically requires that product marketing applications include data from adequate and well controlled clinical trials, which provide substantial evidence of efficacy. In some instances, FDA may condition approval of an NDA on the applicant's agreement to conduct additional clinical trials to further assess the product's safety and effectiveness after approval, to answer unresolved questions. Such post-approval trials are typically referred to as Phase 4 studies. The results of Phase 4 studies can confirm or refute the effectiveness of a product candidate and can provide important safety information.

These Phases may overlap or be combined. For example, a Phase 1/2 clinical trial may contain both a dose-escalation stage and a dose-expansion stage, the latter of which may confirm tolerability at the recommended dose for expansion in future clinical trials (as in traditional Phase 1 clinical trials) and provide insight into the anti-tumor effects of the investigational therapy in selected subpopulation(s).

The manufacture of investigational drugs for the conduct of human clinical trials is subject to current Good Manufacturing Practice, or cGMP requirements. Investigational drugs and active ingredients substances imported into the United States are also subject to FDA regulation. Further, the export of investigational products outside the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

Concurrent with clinical trials, companies usually complete additional nonclinical studies and must also develop additional information about the physical characteristics of the product candidate and finalize a manufacturing process for the product candidate in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate. Further, appropriate packaging must be selected and tested and adequate stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Typically, during the development of oncology therapies, all subjects enrolled in Phase 1 clinical trials are disease-affected patients and, as a result, considerably more information on clinical activity may be collected during such trials than during Phase 1 clinical trials for non-oncology therapies.

The manufacturer of an investigational drug in a Phase 2 or 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access. Investigators must also report certain conflicts of interest to the clinical study sponsor, which the clinical study sponsor must report to FDA.

After completion of the required clinical testing, an NDA is prepared and submitted to FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls.

The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business, provided that certain very specific qualifying criteria are met. Additionally, no application user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved NDA is also subject to annual program fees. The FDA adjusts the user fees on an annual basis, and the fees typically increase annually.

FDA reviews each submitted NDA before it determines whether to file it, based on the agency's threshold determination that it is sufficiently complete to permit substantive review, and FDA may request additional information. The FDA must make a decision on whether to file an NDA within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is filed, FDA begins an in-depth review of the NDA. FDA has agreed to certain performance goals in the review of NDAs. FDA has set a performance goal for reviewing standard applications as within ten months of acceptance of an NDA for filing; and for priority review drugs, within six months of acceptance of an NDA for filing. Drugs may qualify for priority review if they would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA does not always meet its goal dates for standard and priority NDAs, and the review process can be extended by FDA requests for additional information or clarification.

FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an outside advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, FDA will conduct a pre-approval inspection (either in person or remotely) of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA will not approve the product unless cGMP compliance is satisfactory. The FDA also typically inspects (either in person or remotely)

one or more clinical trial sites to ensure compliance with GCP requirements and the integrity of the data supporting safety and efficacy.

After FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter, or CRL, generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for FDA to reconsider the application, such as additional clinical data, additional pivotal clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. In 2025, FDA started publicly releasing complete response letters after issuance, for both products that eventually obtained approval and products that have not yet received approval. If a CRL is issued, the applicant may resubmit the NDA addressing all of the deficiencies identified in the letter, withdraw the application, engage in formal dispute resolution or request an opportunity for a hearing. FDA has committed to reviewing 90% of resubmissions in two or six months depending on the type of information included. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If, or when, the deficiencies identified in the CRL have been addressed to FDA's satisfaction in a resubmission of the NDA, FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

There is no guarantee that FDA will approve an NDA. Moreover, even if marketing authorization of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed, the product may have labeling that includes significant restrictions, warnings, including black box warnings, and contraindications, the regulatory authorities may not approve label claims necessary for successful product marketing, or the approval may be subject to significant conditions of approval, including the requirement of a REMS.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of an NDA supplement or, in some instances, a new NDA, before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

### ***Disclosure of Clinical Trial Information***

Sponsors of clinical trials of FDA regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial, provided that certain criteria are met and certifications are provided. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Failure to follow the applicable disclosure requirements can result in notices of noncompliance and civil monetary penalties.

### ***Expedited Development and Review Programs***

#### ***Fast Track Designation***

Fast track designation may be granted for a product that is intended to treat a serious or life-threatening disease or condition for which preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. The sponsor of an investigational drug product may request that FDA designate the product candidate for a specific indication as a fast-track drug concurrent with, or after, the submission of the IND for the product candidate. FDA must determine if the product candidate qualifies for fast-track designation within 60 days of receipt of the sponsor's request. For fast track products, sponsors may have greater interactions with the FDA and the FDA may potentially initiate review of

sections of a fast track product's NDA before the application is complete, referred to as "rolling review." The sponsor must provide, and the FDA must approve, a schedule for the submission of the application and the sponsor must pay applicable user fees. The FDA may, however, not review applications submitted via rolling review until all sections of the application have been submitted. At the time of NDA filing, the FDA will determine whether to grant priority review designation. FDA will grant such designation if the proposed drug would be a significant improvement in the safety or effectiveness of the treatment, prevention, or diagnosis of a serious condition. Additionally, fast track designation may be withdrawn if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

#### *Accelerated Approval*

Accelerated approval may be granted for a product that is intended to treat a serious or life-threatening condition and that generally provides a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval may be approved on the basis of either 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. The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large studies to demonstrate a clinical or survival benefit. The accelerated approval pathway is contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies to verify and describe the product's clinical benefit. These confirmatory trials must be completed with due diligence. By the date of approval of an accelerated approval product, FDA must specify the conditions for the required post approval studies, including enrollment targets, the study protocol, milestones, and target completion dates. FDA may also, and frequently does, require that the confirmatory Phase 4 studies be commenced prior to FDA granting a product accelerated approval. Reports on the progress of the required Phase 4 confirmatory studies must be submitted to FDA every 180 days after approval. If the trials fail to verify the clinical benefit of the drug or biologics product, the FDA may withdraw approval of the application through a statutorily defined streamlined process. Failure to conduct the required Phase 4 confirmatory studies or to conduct such studies with due diligence, as well as failure to submit the required update reports can subject a sponsor to penalties. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

#### *Breakthrough Therapy Designation*

FDA is also required to expedite the development and review of applications for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new product candidate may request that FDA designate the product candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the product candidate. FDA must determine if the product candidate qualifies for a Breakthrough Therapy Designation within 60 days of receipt of the sponsor's request. The FDA may take certain actions with respect to breakthrough therapies, including but not limited to holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team, granting priority review status or Fast Track Designation, reviewing applications on a rolling basis, and taking other steps to design the clinical studies in an efficient manner. FDA may withdraw breakthrough therapy designation if the conditions of the designation are no longer met.

#### *Orphan Drugs*

Under the Orphan Drug Act, FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making the product for this type of disease or condition will be recovered from sales of the product in the United States. Additionally, to obtain orphan designation, sponsors must present a medically plausible basis for the use of the drug for the rare disease or condition and, if a product is already approved by the FDA that is considered by the FDA to be the same as

the already approved product and is intended for the same indication, a plausible hypothesis for clinical superiority. This hypothesis must be demonstrated to obtain orphan exclusivity.

Orphan drug designation must be requested before submitting an NDA. After FDA grants orphan drug designation, the identity of the drug and its potential orphan use are disclosed publicly by FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The first NDA applicant to receive FDA approval for a particular active moiety to treat a rare disease for which it has such designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication for which it is approved. During the seven-year exclusivity period, FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Other benefits of orphan drug designation include tax credits for certain research and an exemption from the NDA user fee.

### ***Pediatric Information***

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted. However, compliance may be required if approval is sought for other indications for which the product has not received orphan designation.

Alternatively, product candidates intended for the treatment of adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, must submit, with the marketing application, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, gathered using appropriate formulations for each applicable age group, to inform potential pediatric labeling. The FDA may, on its own initiative or at the request of the applicant, grant deferrals or waivers of some or all of this data, as above. Orphan products are not exempt from this requirement.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or nonpatent—for a drug if certain conditions are met. Conditions for exclusivity include FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

### ***Post-Approval Requirements***

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in a manner consistent with the approved labeling. Promotion and advertising must also be truthful and non-misleading, must be adequately substantiated, and with a fair balance between product benefit claims and risks, among other requirements. Over the last few years, FDA has taken a number of actions in the advertising and promotional spaces, including issuing a final rule and a guidance on risk and efficacy disclosures in direct-to-consumer advertising. In 2024, FDA also issued a final guidance on communication of off-label scientific information about approved products. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. In fact, in 2025, FDA increased its enforcement activity regarding promotion and advertising, both in the areas of promotional statements to healthcare providers and direct to consumer advertising. Failure to comply with the laws and regulations governing advertising and promotion can have negative consequences, including FDA and other governmental authority enforcement actions.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition,

quality control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies and list the drugs produced. The information that must be submitted to FDA regarding manufactured products was expanded through the Coronavirus Aid, Relief, and Economic Security, or CARES Act to include the volume of drugs produced during the prior year. Registration with FDA subjects entities to periodic unannounced inspections or remote regulatory assessments by FDA, during which the Agency inspects or assesses manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. Sponsors are further subject to various requirements related to FDA drug shortage and manufacturing volume reporting, supply chain security, such as risk management plan requirements, and the promotion of supply chain redundancy. Legislation and executive actions have also been issued to encourage domestic manufacturing, as well as to decrease drug prices. For instance, FDA approved a plan that was submitted by Florida to import drugs from Canada. Executive orders have also been issued to facilitate and streamline the development of U.S. manufacturing, enhance the inspection of foreign manufacturing facilities, and potentially to increase foreign manufacturing facility user fees.

Changes to the product manufacturing process often require prior FDA approval or notification before being implemented. FDA regulations also require the investigation and correction of any identified deviations from cGMP and specifications, and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers.

### ***The Hatch-Waxman Amendments***

#### ***Orange Book Listing***

Under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch Waxman Amendments, NDA applicants are required to identify to FDA each patent whose claims cover the applicant's drug or approved method of using the drug. Upon approval of a drug, the applicant must update its listing of patents to the NDA in timely fashion and each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. In an effort to clarify which patents must be listed in the Orange Book, in January 2021, Congress passed the Orange Book Transparency Act of 2020, which largely codifies FDA's existing practices into the FD&C Act. Listing patents in the Orange Book that do not qualify for listing can be considered to be anticompetitive conduct and subject to regulatory scrutiny and challenges. The Federal Trade Commission, or FTC, has sent letters to a number of companies with respect to certain patents that agency asserted were improperly listed or inaccurate. The FTC has signaled an increased focus on scrutinizing Orange Book listings as part of its broader efforts to combat practices that may delay generic and biosimilar competition. Listing these unqualified patents (e.g., patents covering unapproved formulations or non-drug product aspects) in the Orange Book has also been the subject of litigation.

Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA or a 505(b)(2) NDA. An ANDA provides for marketing of a drug product that has the same active ingredient(s), strength, route of administration, and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. An approved ANDA product is considered to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved under the ANDA pathway are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug pursuant to each state's laws on drug substitution. 505(b)(2) NDAs are applications that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained the right of reference or use, and allows the 505(b)(2) applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature.

The ANDA or 505(b)(2) NDA applicant is required to certify to the FDA concerning any patents identified for the reference listed drug in the Orange Book. Specifically, the applicant must certify to each patent in one of the following ways: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed

patents, or that such patents are invalid, is called a Paragraph IV certification. For patents listed that claim an approved method of use, under certain circumstances the applicant may also elect to submit a section viii statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents through a Paragraph IV certification, the application will not be approved until all the listed patents claiming the referenced product have expired. If the applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA-holder and patentee(s) within certain specified timeframes (referred to as the “notice letter”). The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice letter. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months from the date the notice letter is received, expiration of the patent, the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed, a decision in the patent case that is favorable to the ANDA or 505(b)(2) NDA applicant, or such shorter or longer period as may be ordered by a court.

The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired. In some instances, an applicant may receive approval prior to expiration of certain non-patent exclusivity if the applicant seeks, and FDA permits, the omission of such exclusivity-protected information from the prescribing information.

#### *Exclusivity*

Upon NDA approval of a new chemical entity, or NCE, which is a drug that contains no active moiety that has been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA or 505(b)(2) application seeking approval of a version of that drug unless the application contains a Paragraph IV certification, in which case the application may be submitted one year prior to expiration of the NCE exclusivity. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA for a generic version of the drug or 505(b)(2) application relying on such drug may be filed before the expiration of the exclusivity period.

Certain changes to an approved drug, such as the approval of a new indication, the approval of a new strength, and the approval of a new condition of use, are associated with a three-year period of exclusivity from the date of approval during which FDA cannot approve an ANDA or 505(b)(2) application for a drug that includes the change. To qualify for three-year exclusivity, there must be new clinical investigations, other than bioavailability studies, supporting the application, that were conducted or sponsored by the applicant, and are deemed by the FDA to be essential to the approval of the application. In some instances, an applicant may receive approval prior to expiration of the three-year exclusivity if the applicant seeks, and FDA permits, the omission of such exclusivity-protected information from the package insert.

#### *Patent Term Extension*

The Hatch Waxman Amendments permit a patent term extension as compensation for patent term lost during the FDA regulatory review process. Patent term extension, however, only applies to one patent per approved product and cannot extend the total term of a patent beyond 14 years from the product’s approval date. After NDA approval, owners of relevant drug patents may apply for the extension. The allowable patent term extension is calculated by taking into account (i) half of the drug’s testing phase (the time between IND application and NDA submission) and (ii) all of the review phase (the time between the full NDA submission and approval), up to a maximum of five years. The time can be reduced for any time the FDA determines the applicant did not pursue approval with due diligence.

The United States Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. The FDA provides a factual assessment of regulatory delay, while the USPTO makes the final determination regarding eligibility and the length of the extension. However, the USPTO may deny an application for extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested.

The application for the extension must be submitted prior to the expiration of the patent. If a patent is set to expire while a patent term extension application is still under review, the patent owner may request an interim extension, which

extends the term by one year per request, up to a maximum of four years. For each interim patent extension granted, the post-approval patent extension is reduced by an equal duration (e.g., one year per interim patent extension). The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

### ***FDA Regulation of Companion Diagnostics***

If use of an in vitro diagnostic is essential to safe and effective use of a drug product, then the FDA generally will require approval or clearance of the diagnostic, known as a companion diagnostic, at the same time that the FDA approves the drug product. FDA has generally required manufacturers of in vitro companion diagnostics intended to select the patients who will respond to cancer treatment to submit a pre-market approval application, or PMA, for that diagnostic device simultaneously with the submission of the drug approval application by the drug manufacturer (which may be the same company as the device manufacturer or a different company). The review of these in vitro companion diagnostics in conjunction with the review of a cancer therapeutic involves coordination of review by the FDA's Center for Drug Evaluation and Research and by the FDA's Center for Devices and Radiological Health. Approval and clearance of a companion diagnostic also requires a high level of coordination between the drug manufacturer and device manufacturer, if different companies. In some cases, FDA may permit the use of a Laboratory Developed Test (LDT) as a companion diagnostic device. In general, tests that meet the definition of an LDT are not subject to FDA oversight and are not required to comply with FDA's medical device regulatory requirements, including PMA approval requirements. However, LDTs must be developed, manufactured, and used in a single clinical laboratory location that has been certified under the Clinical Laboratory Improvement Amendments (CLIA). The laboratory also must be compliant with the CLIA regulations issued by the Centers for Medicare and Medicaid Services (CMS).

For those companion diagnostics that are not LDTs, the PMA process, including the gathering of extensive clinical and preclinical data and device manufacturing information, as well as the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with test data and other information to demonstrate reasonable assurance of the device's safety and effectiveness for its intended use, along with information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to a substantial application fee, which is typically increased annually.

In addition, PMAs must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic has adequate sensitivity and specificity, has adequate specimen and reagent stability, and produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. As part of the PMA review, the FDA will inspect the manufacturer's facilities for compliance with the Quality Management System Regulation, or QMSR, which imposes good manufacturing practice requirements for medical devices, including requirements for established processes, controls, recordkeeping, reporting, documentation and other quality assurance activities.

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or submission of specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also register each of their establishment(s) engaged in design, manufacturing or initial importation activities, including payment of an annual establishment registration fee, and list the device(s) at each such establishment with the FDA. A medical device manufacturer's design and manufacturing processes and those of its contract manufacturers are required to comply with the applicable portions of the QMSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Device manufacturers also have post-market reporting requirements for certain types of adverse events and device malfunctions, as well as for device correction

and removal activities (including recalls). Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

### ***Other Healthcare Laws***

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain general business and marketing practices in the pharmaceutical industry. These laws include anti-kickback, false claims, transparency and health information privacy laws and other healthcare laws and regulations.

The federal Anti-Kickback Statute is a criminal statute that prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The term “remuneration” has been interpreted broadly to include anything of value. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce or reward referrals of federal healthcare program business, including purchases of products paid by federal healthcare programs, the statute has been violated. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, amended the intent element of the federal statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny and enforcement action if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of the facts and circumstances. Additionally, the ACA amended the federal Anti-Kickback Statute such that a violation of that statute is a per se violation of the federal civil False Claims Act. The Beneficiary Inducement Civil Monetary Penalties Law imposes similar restrictions on interactions between the biopharmaceutical industry and federal healthcare program beneficiaries.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, using, or causing to be made or used, a false statement to have a false claim paid, or avoiding, decreasing or concealing an obligation to pay money to the federal government. Intent to deceive is not required to establish liability under the civil False Claims Act. Rather, a claim may be false for deliberate ignorance of the truth or falsity of the information provided or for acts in reckless disregard of the truth or falsity of that information. Civil False Claims Act actions may be brought by the government or may be brought by private individuals on behalf of the government, called “qui tam” actions. If the government decides to intervene in a qui tam action and prevails in the lawsuit, the individual will share in the proceeds from any damages, penalties or settlement funds. If the government declines to intervene, the individual may pursue the case alone if it is not also dismissed by the government. The civil False Claims Act provides for treble damages and a civil penalty for each false claim, such as an invoice or pharmacy claim for reimbursement, which can aggregate into tens and even hundreds of millions of dollars. For these reasons, since 2004, False Claims Act lawsuits against biopharmaceutical companies have increased significantly in volume and breadth, leading to several substantial global civil and criminal settlements of as much as \$3.0 billion regarding certain sales and promotional practices.

The civil False Claims Act has been used to assert liability on the basis of claims made to programs where the federal government reimburses, such as Medicare and Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates and rebates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Private payers have been filing follow-on lawsuits alleging fraudulent misrepresentation, although establishing liability and damages in these cases is more difficult than under the False Claims Act. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

The government may further prosecute conduct constituting a false claim under the criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious or fraudulent. Unlike the civil False Claims Act, the criminal False Claims Act requires proof of intent to submit a false claim.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order or receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, regardless of whether the payor is public or private, or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, we may be subject to healthcare data privacy and security regulations promulgated by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, (“HITECH Act”), and their respective implementing regulations, impose certain requirements on covered entities relating to the privacy, security, and transmission of certain individually identifiable health information known as protected health information. The HIPAA privacy regulations impose certain requirements with respect to the disclosure of protected health information for research purposes, such as clinical trials. Among other things, the HITECH Act and its implementing regulations, made HIPAA’s security standards and certain privacy standards directly applicable to business associates, who, on behalf of covered entities, other than members of a covered entity’s workforce, create, receive, maintain or transmit protected health information for a function or activity regulated by HIPAA. The HITECH Act also strengthened the civil and criminal sanctions that may be imposed against covered entities, business associates, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. Other federal and state laws, such as the California Consumer Privacy Act (“CCPA”) and Washington’s My Health My Data Act, may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts. Since the CCPA was signed into law in 2018, numerous other states, including Virginia, Colorado, Utah and Connecticut, have enacted similar privacy laws that may apply to personal information that we collect or maintain.

Further, pursuant to the ACA, the Centers for Medicare & Medicaid Services, or CMS, issued a final rule implementing the federal Physician Payment Sunshine Act that requires certain manufacturers of prescription drugs, medical devices and medical products to collect and annually report information on certain payments or transfers of value to U.S.-licensed physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The reported data is made available in searchable form on a public website on an annual basis. Failure to submit timely, accurate and complete required information may result in civil monetary penalties. Beginning calendar year 2021, manufacturers must also collect information regarding payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse- midwives for reporting in 2022.

In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products, to report gifts and payments to individual healthcare practitioners, to prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals, and/or to comply with certain compliance requirements.

Some states require the reporting of certain drug pricing information, including information pertaining to and justifying price increases. In addition, certain states require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Certain states and local jurisdictions also require the registration of pharmaceutical sales representatives. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties. Additionally, we may also be subject to state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. If a drug company’s operations are found to be in violation of any such requirements, it may be subject to significant sanctions, including civil and administrative penalties and damages, criminal fines and confinement, disgorgement, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA,

exclusion from participation in federal health care programs, suspension and debarment from government procurement and non-procurement programs, refusal of orders under existing government contracts, integrity oversight and reporting obligations, and reputational harm. Although effective compliance programs can mitigate the risk of investigation and enforcement actions for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

### ***U.S. Healthcare Reform***

In the United States there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was enacted, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, (i) subjected therapeutic biologics to potential competition by lower-cost biosimilars by creating a licensure framework for follow-on biologic products, (ii) proscribed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and therapeutic biologics that are inhaled, infused, instilled, implanted or injected, (iii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) established annual nondeductible fees and taxes on manufacturers of certain branded prescription drugs and therapeutic biologics, apportioned among these entities according to their market share in certain government healthcare programs, (v) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability, (vi) expanded the entities eligible for discounts under the Public Health program, (vii) 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 (viii) established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. There have been legislative and judicial efforts to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. United States federal government agencies also currently face potentially significant spending reductions, which may further impact healthcare expenditures. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, regardless of whether the payor is public or private, will remain in effect through 2032 unless additional Congressional action is taken. Moreover, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be (and have been) reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Recently, there has 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 federal and state legislation designed to, among other things, bring more transparency to product pricing and price increases, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

The Trump and Biden administrations both issued executive orders intended to favor and encourage domestic manufacturing. And on August 16, 2022, former President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products, such as negotiated ceiling prices and penalties for price increases that exceed the rate of inflation that are sold into the Medicare program. Drug price negotiations and other IRA program implementation measures could potentially be affected by the changes in leadership at Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) under the new administration.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Recent legislation has delayed implementation of the aforementioned regulation until January 1, 2032. CMS also published an interim final rule that establishes an MFN Model under which reimbursement for certain Medicare Part B drugs and biologicals would be based on a price that reflects the lowest per capita Gross Domestic Product-adjusted (GDP-adjusted) price of any non-U.S. member country of the Organization for Economic Co-operation and Development (OECD) with a GDP per capita that is at least sixty percent of the U.S. GDP per capita. While this rule now has been rescinded, in November 2025, CMS introduced the GENEROUS Model (launching 2026), which requires manufacturers to provide rebates aligned with most favored nation pricing to participating state Medicaid programs that opt into the program.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints or caps, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. States, such as Maryland, have also established Drug Affordability Review Boards for the purpose of establishing upper payment limits for certain high-cost drugs which could result in reduced reimbursement for those products.

### ***Coverage and Reimbursement***

Patients in the United States and elsewhere generally rely on third-party payors to reimburse part or all of the costs associated with their prescription drugs. Accordingly, market acceptance of our drug products is dependent on the extent to which third-party coverage and reimbursement is available from government health administration authorities (including in connection with government healthcare programs, such as Medicare and Medicaid in the United States), private healthcare insurers and other healthcare funding organizations. Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we may obtain regulatory approval. Coverage decisions may not favor new drug products when more established or lower-cost therapeutic alternatives are already available. Patients are unlikely to use our products unless reimbursement is adequate to cover all or a significant portion of the cost of our drug products.

Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States, although private payors often, but not always, follow CMS's decisions regarding coverage and reimbursement. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time-consuming and costly which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our drug products. Additionally, we may develop, either by ourselves or with collaborators, companion diagnostic tests for our product candidates for certain indications. We, or our collaborators, if any, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved.

The market for our product candidates will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. Competition to be included in such formularies often leads to downward pricing pressures. In particular, third-party payors may refuse to include a particular reference listed drug in their formularies or otherwise restrict patient access to a reference listed drug when a less costly generic equivalent or other alternative is available. Third-party payors may require prior authorizations or failure on another type of treatment before covering a particular drug, particularly with respect to higher-priced drugs. Decreases in third-party reimbursement for a product or a decision by a third-party payor to not cover a product could reduce physician usage of the

product. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations.

The U.S. government, state legislatures and foreign governmental entities have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures and tightening of restrictive policies in jurisdictions with existing controls and measures could exclude or limit our drugs products from coverage and limit payments for pharmaceuticals.

In addition, we expect that the increased emphasis on managed care and cost containment measures in the United States by third-party payors and government authorities to continue, which will place pressure on pharmaceutical pricing and coverage. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more drug products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

### ***Employees***

As of December 31, 2025, we had 79 full-time employees. Of our employees, 53% have an M.D. or a Ph.D. From time to time, we also retain independent contractors to support our organization. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

### **Corporate Information**

We were incorporated under the laws of the State of Delaware in 2016. Our principal executive offices are located in Wilmington, DE. Our website address is [www.preludetx.com](http://www.preludetx.com). Website references in this Annual Report on Form 10-K are inactive, textual references only, and the information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into, this Annual Report on Form 10-K.

The mark “Prelude Therapeutics,” the Prelude logo and all product names are our common law trademarks. All other service marks, trademarks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and tradenames referred to in this Annual Report on Form 10-K appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

### **Available Information**

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, electronically with the U.S. Securities and Exchange Commission, or the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is <http://www.sec.gov>.

We make available free of charge electronic versions of our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports on our website, [preludetx.com](http://www.preludetx.com), as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission, or SEC.

## Item 1A. Risk Factors

### RISK FACTORS

*Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks and uncertainties described below, together with the other information contained in this Annual Report on Form 10-K, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations". The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.*

#### Summary of Risk Factors

Our business is subject to several risks and uncertainties, including those immediately following this summary. Some of these risks are:

- We have incurred significant operating losses since our inception. We expect to incur continued losses for the foreseeable future and may never be profitable.
- We have never generated any revenue and our inability to execute on our business plan may cause you the total or partial loss of your investment.
- As we do not generate any revenue, we are dependent on working capital to fund our business plan, and we will require substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed or on terms acceptable to us, we could be forced to delay, reduce or eliminate our research or drug development programs, any future commercialization efforts or other operations.
- We are highly dependent on the success of our product candidates which are in early development. We have not completed successful late-stage pivotal clinical trials or obtained regulatory approval for any product candidate. We may never obtain approval for any of our product candidates or achieve or sustain profitability.
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and/or commercialization of our product candidates.
- If we experience delays or difficulties in enrolling patients in our clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.
- 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 or abandon further development, limit the commercial profile of an approved product, or result in significant negative consequences following marketing approval, if any.
- 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 for which there is a greater likelihood of success.
- Health care policy changes, including U.S. health care reform legislation, may have a material adverse effect on our business.
- We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.
- Manufacturing pharmaceutical products is complex and subject to product loss for a variety of reasons. We rely on third-party suppliers, including single source suppliers, to manufacture preclinical and clinical supplies of our product candidates and we intend to rely on third parties to produce commercial supplies of any approved product candidate. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

- We may enter into collaborations with third parties for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.
- The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue potential and ability to achieve profitability will be adversely affected.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.
- Our future success depends on our ability to retain key employees and to attract, retain and motivate qualified personnel and manage our human capital.
- We expect 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.
- Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.
- We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.
- If we are unable to obtain and maintain sufficient patent protection for our product candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our product candidates successfully may be adversely affected.
- We may become involved in lawsuits or administrative disputes to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.
- We may not be able to effectively protect or enforce our intellectual property and proprietary rights throughout the world.
- If we are sued for infringing, misappropriating or otherwise violating intellectual property or proprietary rights of third parties, such litigation or disputes could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.
- Rights to improvements to our product candidates may be held by third parties.
- An active and liquid trading market for our common stock may never be sustained. As a result, you may not be able to resell your shares of common stock at or above the purchase price.
- The market price of our common stock has been and is likely to continue to be highly volatile, which could result in substantial losses for purchasers of our common stock.
- Our principal stockholders and management own a significant percentage of our stock and can exert significant control over matters subject to stockholder approval.
- We are a “smaller reporting company” and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

## Risks Related to Our Financial Position and Need for Capital

***We have incurred significant operating losses since our inception. We expect to incur continued losses for the foreseeable future and may never be profitable.***

Investment in drug development is a highly speculative undertaking and involves a substantial degree of risk. For the year ended December 31, 2025, we reported a net loss of \$99.5 million, compared to a net loss of \$127.2 million for the year ended December 31, 2024. As of December 31, 2025, we had an accumulated deficit of \$683.1 million. We have not yet commercialized any product, and we do not expect to generate revenue from sales of any products for several years, if at all. We expect to continue to incur significant research and development and other expenses related to our ongoing operations.

Since our inception, we have focused substantially all of our efforts and financial resources on the research, preclinical and clinical development of our product candidates, and our research efforts on other potential product candidates. As of December 31, 2025, our cash, cash equivalents, and marketable securities were \$103.2 million.

We expect to incur operating losses for the foreseeable future, particularly as we advance our product candidates through clinical development. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to incur research and development expenses in connection with our additional planned clinical trials for our lead product candidates and the development and subsequent INDs of other future product candidates we may choose to pursue. In addition, if we obtain marketing approval for any of our product candidates, we will incur significant sales, marketing and outsourced manufacturing expenses in connection with the commercialization. As a result, we expect to continue to incur significant operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. We expect our financial condition and operating results to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

***We have never generated any product revenue and our inability to execute on our business plan may cause you the total or partial loss of your investment.***

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any product revenue and we do not know when, or if, we will generate any product revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval for, and begin to sell, one or more of our product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- complete successful clinical trials for our product candidates;
- initiate and successfully complete all safety, pharmacokinetic and other studies required to obtain U.S. and foreign marketing approval for our product candidates;
- initiate and complete successful later-stage clinical trials that meet their clinical endpoints;
- obtain favorable results from our clinical trials and apply for and obtain marketing approval for our product candidates;
- establish licenses, collaborations, or strategic partnerships that may increase the value of our programs;
- successfully manufacture or contract with others to manufacture our product candidates;
- commercialize our product candidates, if approved, by building a sales force or entering into collaborations with third parties;
- submit INDs that are made effective by the FDA;
- obtain, maintain, protect and defend our intellectual property portfolio; and
- achieve market acceptance of our successful product candidates with the medical community and with third-party payors.

To become and remain profitable, we must succeed in designing, developing, and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials for our product candidates, designing additional product candidates, establishing arrangements with third parties for the manufacture of clinical supplies of our product candidates, obtaining marketing approval for our product candidates and manufacturing, marketing and selling any products for which we may obtain marketing approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

In cases where we are successful in obtaining regulatory approval to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, or if, we will be able to achieve profitability. If we decide to or are required by the FDA or regulatory authorities in other jurisdictions to perform studies or clinical trials in addition to those currently expected, or if there are any delays in establishing appropriate manufacturing arrangements for, in initiating or completing our clinical trials for, or in the development of, any of our product candidates, our expenses could increase materially and profitability could be further delayed.

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

***As we do not generate any revenue, we are dependent on working capital to fund our business plan, and we will require substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed or on terms acceptable to us, we could be forced to delay, reduce or eliminate our research or drug development programs, any future commercialization efforts or other operations.***

We expect to continue to incur expenses in connection with our ongoing activities, particularly as we advance our product candidates through clinical development and seek to design additional product candidates from our discovery programs. We expect to incur continued expenses as we continue our research and development, initiate additional clinical trials, and seek marketing approval for our lead programs and our other product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on favorable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. For example, we received capital in connection with the exclusive option agreement entered into with Incyte Corporation (“Incyte”) in November 2025 in exchange for the option to acquire certain rights, titles and interests related to our mutative selective JAK2V617F inhibitor program. If we are unable to raise capital when needed or on favorable terms, we could be forced to delay, reduce or eliminate our research and development programs, our commercialization plans or other operations.

We believe that our existing cash, cash equivalents, and marketable securities will enable us to fund our operating expenses, and capital expenditure requirements for at least the next twelve months from the filing date of this Annual Report on Form 10-K. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Changes beyond our control may occur that would cause us to use our available capital before that time, including changes in and progress of our drug development activities and changes in regulation. Our future capital requirements will depend on many factors, including:

- the progress, timing and results of preclinical studies and clinical trials for our current or any future product candidates;

- the extent to which we develop, in-license or acquire other pipeline product candidates or technologies;
- the number and development requirements of other product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the costs, timing and outcome of obtaining regulatory approvals of our current or future product candidates and any companion diagnostics we may pursue;
- the scope and costs of making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our current or future product candidates;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or future product candidates;
- the cost associated with commercializing any approved product candidates, including establishing sales, marketing and distribution capabilities;
- the cost associated with completing any post-marketing studies or trials required by the FDA or other regulatory authorities;
- the revenue, if any, received from commercial sales of our product candidates that receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims that we may become subject to, including any litigation costs and the outcome of such litigation;
- the costs associated with potential product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims; and
- to the extent we pursue strategic collaborations, including collaborations to commercialize our product candidates, our ability to establish and maintain collaborations on favorable terms, if at all, as well as the timing and amount of any milestone or royalty payments we are required to make or are eligible to receive under such collaborations, if any.

We will require additional capital to complete our planned clinical development programs for our current product candidates to obtain regulatory approval. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or product candidates or we may be unable to take advantage of future business opportunities. Furthermore, 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.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to continue to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends.

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

reduce or terminate our research, product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***Unstable market, economic and political conditions may have serious adverse consequences on our business, financial condition, results of operations and prospects.***

Our business, financial condition, results of operations and prospects could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, service providers, manufacturers or other partners and there is a risk that one or more would not survive or be able to meet their commitments to us under such circumstances. Global credit and financial markets have experienced volatility and disruptions in the past several years partly due to widespread health concerns, pandemics and other outbreaks of illness as well as the ongoing conflicts in Ukraine and the Middle East and increasing tensions in Central and South America, including recent U.S. military operations in Venezuela. Such volatility includes severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, inflation, increases in unemployment rates and uncertainty about economic stability. There can be no assurances that further deterioration in credit and financial markets and confidence in economic conditions will not occur. For example, U.S. debt ceiling and budget deficit concerns have increased the possibility of additional credit-rating downgrades and economic slowdowns, or a recession in the United States. Although U.S. lawmakers passed legislation to raise the federal debt ceiling on multiple occasions, including a suspension of the federal debt ceiling in June 2023, ratings agencies have lowered or threatened to lower the long-term sovereign credit rating of the United States. The impact of this or any further downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions. Moreover, the uncertainty surrounding government funding debates and debt-ceiling negotiations can negatively affect market conditions, investor sentiment, and the liquidity of small-cap and microcap issuers such as ours. Accordingly, any future federal government shutdown or protracted budget impasse could materially and adversely affect our regulatory compliance, financing options and capabilities, and overall financial condition. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

**Risks Related to Design and Development of our Product Candidates**

***We are highly dependent on the success of our product candidates that are in clinical development. We have not completed successful late-stage pivotal clinical trials or obtained regulatory approval for any product candidate. We may never obtain approval for any of our product candidates or achieve or sustain profitability.***

Our future success is highly dependent on our ability to obtain regulatory approval for, and then successfully commercialize, our product candidates. We are early in our development efforts. We currently have no products that are approved for sale in any jurisdiction. There can be no assurance that our product candidates in development will achieve success in their preclinical or clinical trials or obtain regulatory approval. Regulators may also request additional studies, data, and information, that we may need to develop and which were not originally planned. Any delays in clinical studies, obtaining regulatory approval, or if we never initiate clinical studies or obtain regulatory approval, could have a material adverse effect on our business, financial condition and results of operations.

The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- acceptance of INDs by the FDA or other similar clinical trial applications from foreign regulatory authorities for our future clinical trials for our pipeline product candidates;
- timely and successful enrollment of patients in, and completion of, clinical trials with favorable results;
- demonstration of safety, efficacy and acceptable risk-benefit profiles of our product candidates to the satisfaction of the FDA and foreign regulatory agencies;
- our ability, or that of our collaborators, to develop and obtain clearance or approval of companion diagnostics, on a timely basis, or at all;
- receipt and related terms of marketing approvals from applicable regulatory authorities, including the completion of any required post-marketing studies or trials;

- raising additional funds necessary to complete clinical development of and commercialize our product candidates;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- developing and implementing marketing and reimbursement strategies;
- establishing sales, marketing and distribution capabilities and 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;
- effectively competing with other therapies;
- obtaining and maintaining third-party payor coverage and adequate reimbursement;
- protecting and enforcing our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the products following approval and compliance with any post-approval requirements and commitments, including REMS and post-approval studies required by FDA.

Many of these factors are beyond our control, and 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, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. For example, our business could be harmed if results of our clinical trials vary adversely from our expectations.

***Drug development involves a lengthy and expensive process, and clinical testing is uncertain as to the outcome.***

We currently have several product candidates in preclinical development, and the risk of failure for each is high. We are unable to predict when or if our product candidates will prove effective or safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome.

A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials or of clinical trials of the same product candidates in other indications, and interim or preliminary results of a clinical trial do not necessarily predict final results. Later-stage clinical trials could differ in significant ways from early-stage clinical trials, including changes to inclusion and exclusion criteria, efficacy endpoints, dosing regimen and statistical and clinical design. Studies may also be subject to confounding factors that make it difficult to interpret the results or that could impact the reliability of the results.

***We may incur additional costs or experience delays in completing, or ultimately be unable to complete the development and/or commercialization of our product candidates.***

Before we can initiate clinical trials of a product candidate in any indication, we must submit the results of preclinical studies to the FDA or to comparable foreign authorities, respectively, along with other information, including information about the product candidate's chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or comparable foreign regulatory filings.

The FDA may require us to conduct additional preclinical studies or additional manufacturing development for any product candidate before it allows us to initiate subsequent clinical trials under any IND, which may lead to additional delays and increase the costs of our preclinical development programs.

Any delays in the commencement or completion of our clinical trials could significantly affect our product development costs. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize our product candidates, including:

- regulators, IRBs, or ethics committees, or ECs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA may disagree as to the design or implementation of our clinical trials or with our proposed dose for any of our pipeline programs. For instance, in the oncology space, FDA assesses not only maximum tolerated dose but also dose optimization, with the issuance of guidance on this topic. FDA has also expressed a preference for randomized controlled clinical trials to support accelerated approval, rather than single arm trials with response endpoint;
- delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective contract research organizations, or CROs, and prospective trial sites;
- clinical trials for our product candidates that may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, delay or halt clinical trials or abandon product development programs;
- lack of adequate funding to continue the clinical trial;
- the number of patients required for clinical trials for our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or may be lower than we anticipate due to challenges in recruiting and enrolling suitable patients that meet the study criteria, participants may drop out of these clinical trials at a higher rate than we anticipate or may not follow trial procedures or the duration of these clinical trials may be longer than we anticipate;
- competition for clinical trial participants from investigational and approved therapies may make it more difficult to enroll patients in our clinical trials;
- difficulties in maintaining contact with patients after treatment, resulting in incomplete data;
- potential failures to obtain regulatory approval of companion diagnostic tests, if required, on a timely basis, or at all;
- potential failures by our third-party contractors to meet their contractual obligations to us in a timely manner, or at all, or failure to comply with regulatory requirements;
- the suspension or termination of clinical trials for our product candidates for various reasons, including a finding by us or by a Data Monitoring Committee for a trial that the participants are being exposed to unacceptable health risks;
- undesirable or unexpected side effects or other unexpected characteristics from our product candidates, causing us or our investigators, regulators or IRBs/ECs to suspend or terminate the trials;
- the cost of clinical trials for our product candidates may be greater than we anticipate;
- changes to clinical trial protocol;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials for our product candidates may be insufficient or inadequate and result in delays or suspension of our clinical trials; and
- the impact of any widespread outbreak of a communicable disease, which may slow potential enrollment, reduce the number of eligible patients for clinical trials, confound trial results, or reduce the number of patients that remain in our trials.

Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial or obtain timely marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured or will be completed on schedule, or at all. For example, the FDA may place a partial or full clinical hold on any of our clinical trials for a variety of reasons, including safety concerns and noncompliance with regulatory requirements. If we are not able to complete successful clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize our product candidates.

Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

***If we experience delays or difficulties in enrolling patients in our clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.***

We may not be able to initiate or continue our clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. In addition, some of our competitors currently have ongoing clinical trials for product candidates that would treat the same patients as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- our ability to recruit clinical trial investigators of appropriate competencies and experience;
- the incidence and prevalence of our target indications;
- clinicians' and patients' awareness of, and perceptions as to the potential advantages and risks of our product candidates in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- competing studies or trials with similar eligibility criteria;
- invasive procedures required to enroll patients and to obtain evidence of the product candidate's performance during the clinical trial;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria defined in the protocol for the trial in question;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- efforts to facilitate timely enrollment in clinical trials;
- disruptions caused by and the willingness of patients to enroll in a clinical trial during outbreaks of contagious disease;
- whether we are subject to a partial or full clinical hold on any of our clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll and maintain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs, which would cause the value of our company to decline and limit our ability to obtain additional financing.

***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 or abandon further development, limit the commercial profile of an approved product, or result in significant negative consequences following marketing approval, if any.***

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could result in the delay, suspension or termination of clinical trials by us or regulatory authorities for a number of reasons or could result in a FDA determination not to approve the product. Furthermore, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates or those of our competitors may only be uncovered with a significantly larger number of patients exposed to the drug.

Additionally, due to the high mortality rates of the cancers for which we are initially pursuing development and the pretreated nature of many patients, a material percentage of patients in clinical trials may die during a trial, which could impact the development of product candidates. If we elect or are required to delay, suspend or terminate any clinical trial, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from this product candidate will be delayed or eliminated. Adverse events observed in clinical trials could prevent approval of the product or, if approved, hinder or prevent market acceptance of our product candidates. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for our product candidates, if approved. We may also be required to modify our study plans based on findings in our clinical trials. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial. Many drugs that initially showed promise in early stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions, require additional testing to confirm these determinations, require more restrictive labeling, or deny regulatory approval of the product candidate.

It is possible that, as we test our product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of our product candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

In addition, if any of our product candidates receive marketing approval, and we or others later identify undesirable side effects caused by treatment with such drug, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of the drug;
- we may be required to recall a product or change the way the drug is administered to patients;
- regulatory authorities may require additional warnings in the labeling, such as a contraindication or a boxed warning, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients;
- we may be subject to regulatory investigations and government enforcement actions;
- the drug could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

***Preliminary, interim and topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials. These updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to

change following a more comprehensive review of the data related to the particular study or trial. Additionally, 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. Therefore, positive interim results in any clinical trial may not be predictive of such results in the completed study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline 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. 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, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Adverse changes between preliminary or interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock. See the description of risks under the heading “Risks Related to our Common Stock” for more disclosure related to the risk of volatility in our stock price.

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 value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material, or otherwise appropriate, information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize any product candidates may be harmed, which could harm 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 for which there is a greater likelihood of success.***

Because we have limited financial and managerial 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. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. As an example, on November 4, 2025, we announced that we were pausing the clinical development of our SMARCA2 degrader program, which is comprised of PRT3789 and PRT7732, for strategic reasons and not due to safety or regulatory concerns. 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.

***We may not be successful in our efforts to design additional potential product candidates.***

A key element of our strategy is to identify molecular targets and intervention points leading to treatment failure and then apply our expertise of cancer biology and medicinal chemistry, as well as our in-depth understanding of the current landscape of oncology treatments, to design solutions that can be precisely tailored in a target class agnostic fashion. The therapeutic design and development activities that we are conducting may not be successful in developing product candidates that are safe and effective in treating cancer or other diseases. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the target selection methodology used may not be successful in identifying potential product candidates;
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will obtain marketing approval or achieve market acceptance; or
- potential product candidates may not be effective in treating their targeted diseases.

Research programs to identify and design new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. If we are unable to identify and design suitable product candidates for preclinical and clinical development, we will not be able to obtain revenues from the sale of products in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

### **Risks Related to Government Regulation**

***The development and commercialization of pharmaceutical products are subject to extensive regulation, and we may not obtain regulatory approvals for any product candidates, on a timely basis or at all.***

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to our product candidates are subject to extensive regulation. Marketing approval of drugs in the United States requires the submission of an NDA to the FDA, and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the NDA for that product. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls. Our product candidates must be approved by comparable regulatory authorities in other jurisdictions prior to commercialization.

FDA approval of an NDA is not guaranteed, and the review and approval process is an expensive and uncertain process that may take several years. Of the large number of drugs in development in the United States, only a small percentage will successfully complete the FDA regulatory approval process and will be commercialized. Accordingly, there can be no assurance that any of our product candidates will receive regulatory approval in the United States, or other jurisdictions.

The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for NDA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage. The results of preclinical and early clinical trials of any product candidate may not be predictive of the results of our later-stage clinical trials.

Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits, and failure in clinical trials can occur at any stage. Companies in the pharmaceutical industry frequently suffer setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval.

The FDA could delay, limit or deny approval of a product candidate for many reasons, including because the FDA:

- may not deem our product candidate to be safe and effective;
- determines that the product candidate does not have an acceptable benefit-risk profile;
- determines, in the case of an NDA seeking accelerated approval, that the NDA does not provide evidence that the product candidate represents a meaningful advantage over available therapies;
- determines that the objective response rate, or ORR, and duration of response are not clinically meaningful;
- may require that we do additional work to determine the optimal dose;
- may not agree that the data collected from preclinical studies and clinical trials are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval and may impose requirements for additional preclinical studies or clinical trials;
- may determine that adverse events experienced by participants in our clinical trials represent an unacceptable level of risk;
- may determine that population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;

- may not agree with the design of our clinical or preclinical trials, or may not agree with the method of data analysis;
- may not accept clinical data from trials, which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States or the population is different than in the United States;
- may disagree regarding the formulation, labeling and/or the specifications;
- may not approve the manufacturing processes associated with our product candidate or may determine that a manufacturing facility does not have an acceptable compliance status;
- may change approval policies or adopt new regulations; or
- may not file a submission due to, among other reasons, the content or formatting of the submission.

In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials, and the review process. For example, the Oncology Center of Excellence, or OCE, within the FDA advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. This shift from the prior approach, which generally determined the maximum tolerated dose, may require sponsors to spend additional time and resources to further explore a product candidate's dose-response relationship to facilitate optimum dose selection in a target population. Other OCE initiatives have included Project FrontRunner, an initiative with a goal of developing a framework for encouraging sponsors to consider developing cancer drugs in the earlier advanced setting rather than for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options. We are considering these and any other policy changes, including initiatives with respect to accelerated approval and to coordinate review of oncology products among international regulators, as they relate to our programs.

We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for our clinical product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, our commercial prospects will be harmed and our ability to generate revenues will be materially impaired which would adversely affect our business, prospects, financial condition and results of operations.

***The accelerated approval pathway for our product candidates may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.***

Under the FDA's accelerated approval program, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. We may seek accelerated approval for one or more of our product candidates on the basis of ORR with an acceptable duration of response, a surrogate endpoint that we believe is reasonably likely to predict clinical benefit.

For drugs granted accelerated approval, post-marketing confirmatory trials are required to describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence. By the date of approval of an accelerated approval product, the FDA must specify the conditions for the required post approval studies, including enrollment targets, the study protocol, milestones, and target completion dates. The FDA may also, and frequently does, require that the confirmatory Phase 4 studies be commenced prior to the FDA granting a product accelerated approval. Reports on the progress of the required Phase 4 confirmatory studies must be submitted to the FDA every 180 days after approval. If the trials fail to verify the clinical benefit of the drug or biologics product, the FDA may withdraw approval of the application through a statutorily defined streamlined process or we may voluntarily decide to withdraw the product from the market. Failure to conduct the required Phase 4 confirmatory studies or to conduct such studies with due diligence, as well as failure to submit the required update reports can subject a sponsor to penalties. The

FDA may also require that we conduct additional confirmatory studies, which would require a significant dedication of time and resources.

If any of our competitors were to receive full approval on the basis of a confirmatory trial for an indication for which we are seeking accelerated approval before we receive accelerated approval, the indication we are seeking may no longer qualify as a condition for which there is an unmet medical need and accelerated approval of our product candidate would be more difficult, or impossible, to obtain. Also, the existing treatment landscape may change, which may necessitate that we conduct additional studies or collect additional data to obtain accelerated approval. Moreover, the FDA may withdraw approval of our product candidate approved under the accelerated approval pathway if, for example:

- the trial or trials required to verify the predicted clinical benefit of our product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug;
- other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use;
- we fail to conduct any required post-approval trial of our product candidate with due diligence; or
- we disseminate false or misleading promotional materials relating to the relevant product candidate.

Recently, the accelerated approval pathway has come under scrutiny within the FDA, the Department of Health and Human Services, and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, FDA convened its Oncologic Drugs Advisory Committee to review what the FDA has called dangling or delinquent accelerated approvals where confirmatory studies have not been completed or where results did not confirm benefit. In addition, the OCE implemented Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in approval and post-marketing processes, with the goal to enhance the balance of access and verification of benefit for therapies available to patients with cancer and hematologic malignancies. We may see further legislative or regulatory changes to this program in the future.

***There may be future changes in legal and regulatory requirements that may materially impact our results of operation.***

Changes in legal and regulatory requirements may introduce new risks into our operations and future prospects, which we are not able to currently anticipate. By example, changes taking place in the United States associated with the current federal administration, as well as changes in legal standards, including the reduced level of judicial deference due to administrative agencies following a 2024 Supreme Court decision, may introduce uncertainties with respect to our current and future operations and our future likelihood of success. New federal or state laws or regulations may be passed or have been passed, or laws and regulations may be and have been enforced differently than they were before, which may expose us to additional legal and regulatory risk or uncertainty and require the expenditure of additional resources to ensure that we are able to comply. Such actions could also adversely restrict our business and operations. There could also be changes in FDA's approval standards that could impact our ability to obtain product approval and market our product candidates within the currently anticipated timeframes or otherwise impact the competitive market for our product candidates. Such changes may necessitate the conduct of additional development work, including preclinical and clinical trials, and manufacturing development. By example, for products intended for rare and serious diseases with unmet medical needs, FDA is authorized to exercise regulatory flexibility when making a medical risk-benefit judgment. It is possible that whether and how FDA exercises any regulatory flexibility, including with respect to specialized pathways, such as accelerated approval, and with respect to our product candidates may change, which could impact our ability to obtain product approval. Further, legal and regulatory changes may impact how we may market and sell our products in the future, if they are approved, as well as how they are reimbursed. Moreover, there have and could be further changes in the federal workforce and agency policies that may result in regulatory delays, including with respect to FDA's review of marketing applications and other submissions, and that may impact the ability to communicate with and obtain guidance from the agencies.

***Our failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed in those jurisdictions, and any approval we are granted for our product candidates in the United States would not assure approval of product candidates in foreign jurisdictions.***

In order to market and sell our products in any jurisdiction outside the United States, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product obtain pricing and reimbursement approval. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to submit for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

***We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.***

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as “orphan drugs.” Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or if the disease or condition affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing the drug for the type of disease or condition will be recovered from sales of the product in the United States. When seeking orphan drug designation, sponsors must also provide medically plausible basis for the use of the drug for the rare disease or condition.

Orphan drug designation can provide opportunities for financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Additionally, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same approved indication for seven years, except in certain circumstances, such as a showing of clinical superiority (i.e., another product is safer, more effective or makes a major contribution to patient care) over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. Competitors, however, may receive approval of different products for the same indication for which the orphan product has exclusivity, or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity.

We may apply for an orphan drug designation in the United States or other geographies for our product candidates, where such designation is available, in the future. However, obtaining an orphan drug designation can be difficult, and we may not be successful in doing so. Even if we obtain orphan drug designation for our product candidates in specific indications, we may not be the first to obtain regulatory approval of these product candidates for the orphan-designated indication, due to the uncertainties associated with developing pharmaceutical products, in which case we may be blocked by other’s periods of regulatory exclusivity or may need to demonstrate clinical superiority, which we may not be able to do. We also may never obtain orphan drug exclusivity, even if we obtain a designation. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for orphan designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan drug designation does not ensure that we will receive marketing exclusivity in a particular market, and we cannot assure you that any future application for orphan drug designation in any other geography or with respect to any other product candidate will be granted. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. Moreover, the scope of and protection offered by orphan drug exclusivity, and any advantages of the designation, may change.

***A Breakthrough Therapy Designation by the FDA for any of our current or future product candidates may not lead to a faster development or regulatory review or approval process, and it would not increase the likelihood that the product candidate will receive marketing approval.***

We may seek a Breakthrough Therapy Designation for one or more of our current or future product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and

communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the NDA.

Designation as a breakthrough therapy is at the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a drug may not result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. Further, even if any of our product candidates do receive Breakthrough Therapy Designation, or any other special designation intended to facilitate development, we will need to be prepared for a more rapid pace of development, including with respect to manufacturing and any necessary companion diagnostics, which we may not be able to do. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened.

***If we are unable to successfully develop, validate, obtain regulatory approval of and commercialize companion diagnostic tests for any product candidates that require such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates.***

A companion diagnostic is a medical device, often an *in vitro* device, which provides information that is essential for the safe and effective use of a corresponding therapeutic drug product. A companion diagnostic can be used to identify patients who are most likely to benefit from the therapeutic product. In the future, we may evaluate opportunities to develop, either by ourselves or with collaborators, companion diagnostic tests for our product candidates for certain indications.

A companion diagnostic is generally developed in conjunction with the clinical program for an associated therapeutic product. To date, the FDA has required premarket approval of the vast majority of companion diagnostics for cancer therapies, except in limited cases where the diagnostic is considered an LDT. LDTs are generally not subject to FDA jurisdiction, but remain subject to CLIA regulatory requirements. Generally, when a companion diagnostic is essential to the safe and effective use of a drug product, the FDA requires that the companion diagnostic be approved before or concurrent with approval of the therapeutic product and before a product can be commercialized. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect.

Development of a companion diagnostic could include additional meetings with regulatory authorities, such as a pre-submission meeting and the requirement to submit an investigational device exemption application. In the case of a companion diagnostic that is designated as a "significant risk device," approval of an investigational device exemption by the FDA and IRB is required before such diagnostic is used in conjunction with the clinical trials for a corresponding product candidate.

To be successful in developing, validating, obtaining approval of and commercializing a companion diagnostic, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. We have no prior experience with medical device or diagnostic test development. If we choose to develop and seek FDA approval for companion diagnostic tests on our own, we will require additional personnel. If we seek to develop an LDT as a companion diagnostic, we will need to establish a CLIA-certified clinical laboratory and ensure both the laboratory and LDT comply with the applicable CLIA regulations. For companion diagnostics that are not LDTs, we may rely on third parties for the design, development, testing, validation and manufacture of companion diagnostic tests for our therapeutic product candidates that require such tests, the application for and receipt of any required regulatory approvals, and the commercial supply of these companion diagnostics. If these parties are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, we may be unable to enroll enough patients for our current and planned clinical trials, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. For any product candidate for which a companion diagnostic is necessary to select patients who may benefit from use of the product candidate, any failure to successfully develop a companion diagnostic may cause or contribute to delayed enrollment of our clinical trials and may prevent us from initiating a pivotal trial. In addition, the commercial success and approval of any of our product candidates that require a companion diagnostic will be tied to and dependent upon the receipt of required regulatory approvals and the continued ability of such

third parties to make the companion diagnostic commercially available to us on reasonable terms in the relevant geographies. Any failure to do so could materially harm our business, results of operations and financial condition.

***If we decide to pursue a Fast Track Designation by the FDA, it may not lead to a faster development or regulatory review or approval process.***

We may seek Fast Track Designation for one or more of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

***Even if we obtain marketing approval for our product candidates, the terms of approvals, ongoing regulation of our products or other post-approval restrictions may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.***

Any product candidates for which we receive accelerated approval from the FDA are required to undergo one or more confirmatory clinical trials. If such a product candidate fails to meet its safety and efficacy endpoints in such confirmatory clinical trials, the regulatory authority may withdraw its approval. There is no assurance that any such product candidate will successfully advance through its confirmatory clinical trial(s). Therefore, even if a product candidate receives accelerated approval from the FDA, such approval may be withdrawn at a later date.

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, which may include the requirement to implement a REMS or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product.

We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling, among other requirements. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. Over the last year, FDA has increased its enforcement of promotional and advertising requirements, especially in the area of direct to consumer advertising. Accordingly, there may be an increased risk of enforcement should promotional communications not comply with FDA's requirements.

In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our CMOs could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we obtain marketing approval for one or more of our product candidates, we and our CMOs will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. As a result, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

***Any product candidate for which we obtain marketing approval will be subject to ongoing enforcement of post-marketing requirements by regulatory agencies, and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.***

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping.

The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug products, both before and after approval, including requirements pertaining to clinical trials, marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Violations of such requirements may lead to investigations alleging violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, and other statutes, including the False Claims Act and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements either before or after approval, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various adverse results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals or clinical trials;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- debarment or exclusion;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

***Our current and future relationships with customers and third-party payors may be subject to applicable anti-kickback, fraud and abuse, transparency, health privacy, and other healthcare laws and regulations, which could expose us to significant sanctions, including criminal, civil, and administrative penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, including physicians, and third-party payors will 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 providers, 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 any product candidates, as well as market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations that may be applicable to our business include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, 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 a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the federal civil False Claims Act, which can be enforced by individual whistleblowers in “qui tam” actions brought on behalf of the government, and criminal false claims laws and the civil monetary penalties law, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government;
- HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, regardless of the payor (*e.g.*, public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose requirements on certain covered entities, including healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure, of individually identifiable health information, relating to the privacy, security, and transmission of such individually identifiable health information;
- The ACA requires certain manufacturers of drugs, devices, biologics and medical supplies to annually report to CMS information related to certain payments and other transfers of value provided to teaching hospitals and to U.S.-licensed physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives. Applicable manufacturers also must report ownership and investment interests held by physicians and their immediate family members; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, and analogous non-U.S. fraud and abuse laws and regulations 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 or the Compliance Program Guidance for Pharmaceutical Manufacturers published by the U.S. Department of Health & Human Services, Office of Inspector General; to implement gift bans, and to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, including price increases. Some state and local laws require the registration of pharmaceutical sales representatives. Various state and non-U.S. laws also govern the privacy and security of individuals’ health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may 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 or the operations of vendors or third parties working on our behalf are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject

to significant sanctions, including civil and administrative penalties and damages, criminal fines and confinement, disgorgement, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid and other federal healthcare programs, suspension and debarment from government procurement and non-procurement programs, refusal of orders under existing government contracts, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, 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 healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to significant criminal, civil and administrative sanctions, including exclusion from participation in government funded healthcare programs, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

***Health care policy changes, including U.S. health care reform legislation, may have a material adverse effect on our business.***

In response to perceived increases in health care costs in recent years, there have been and continue to be proposals by the federal government, state governments, regulators, and third-party payors to control these costs and, more generally, to reform the U.S. health care system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. Further, while the United States has begun experimenting with pay-for-performance rather than fee-for-service models and has been embracing many shared-risk arrangements, CMS and OIG specifically excluded manufacturers and others from utilizing certain beneficial exceptions and safe harbors. The exclusion of manufacturers from utilizing these exceptions and safe harbors will not allow us to avail ourselves of immunity from liability under the laws, potentially inviting greater scrutiny over our shared risk arrangements.

The ACA imposes certain stringent compliance, recordkeeping, and reporting requirements on companies in various sectors of the life sciences industry, and enhanced penalties for non-compliance. Despite the ACA going into effect over a decade ago, there have been numerous legal and Congressional challenges to the law's provisions and the effect of certain provisions have made compliance costly.

We cannot predict what additional new legislation, agency priorities, and rulemakings may be on the horizon as the United States continues to reassess how it pays for healthcare. As a result, we cannot quantify or predict what impact any changes might have on our business and results of operations. However, any changes that restrict coverage or lower reimbursement for our products could materially and adversely affect our business, financial condition and results of operations.

Other legal, regulatory and commercial policy influences are subjecting our industry to significant changes, and we cannot predict whether new regulations or policies will emerge from U.S. federal or state governments, foreign governments, or third-party payors. Government and commercial payors may, in the future, consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect reimbursement for healthcare products such as our systems. These policies have included and may in the future include: basing reimbursement policies and rates on clinical outcomes, the comparative effectiveness, and costs, of different treatment technologies and modalities; imposing price controls and taxes on medical device providers; and other measures. These policies culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which, among other things, allows the U.S. Department of Health and Human Services, or HHS, to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D. The IRA requires manufacturers of selected drugs to negotiate discounted prices with the Secretary of HHS. Failure of a manufacturer to reach an agreement can subject manufacturers to an excise tax or withdraw of all drug products from coverage under Medicare and Medicaid. The negotiated prices, which will first become effective in 2026 and were capped at a statutory ceiling price beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions began taking effect in 2023, have been subject to multiple legal challenges, and have since been allowed by Congress to expire. Future significant changes in the healthcare systems in the United States or elsewhere could also have a negative impact on the demand for our current and future products. These include changes that may reduce reimbursement rates for our products and changes that may be proposed or implemented by the current or future laws or regulations. It is unclear exactly what, if any, healthcare reform measures of the new administration will have on our business. For example, drug price negotiations and other IRA program implementation measures could potentially be affected by the changes in leadership at Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) under the new administration. In another example, the CMS issued an interim final rule on November 27, 2020, implementing a Most

Favored Nation, or MFN, payment model under which reimbursement for certain Medicare Part B drugs and biologicals would be based on a price that reflects the lowest per capital Gross Domestic Product-adjusted, or GDP-adjusted, price of any non-U.S. member country of the Organization for Economic Co-operation and Development, or OECD, with a GDP per capita that is at least sixty percent of the U.S. GDP per capita. Although this rule has since been rescinded, in November 2025, CMS introduced the GENEROUS Model, which is scheduled to launch in January 2026 and run for five years, pursuant to which manufacturers will provide supplemental rebates aligned with MFN pricing to participating in state Medicaid programs that opt into the program in exchange for standardized coverage criteria across all participating states.

***Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenues, if any.***

In some countries, particularly the countries of the European Union, or the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing and reimbursement approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other countries allow companies to determine the prices for their medicines but monitor and control company profits and may limit or restrict reimbursement and can include retrospective rebates to the government. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained, or vice versa. Reference pricing used by various EU member states and parallel trade, such as arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products.

***Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates and products outside of the United States and require us to develop and implement costly compliance programs.***

We currently are subject to a number of government laws and regulations and, in the future, could become subject to new government laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect our business, cash flow, results of operations, financial condition and prospects. For example, if we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate, including anti-corruption laws. The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business, and third-party agents acting on their behalf, from paying, offering, or authorizing the payment or offering of anything of value, directly or indirectly, to any foreign official, foreign political party or official thereof, or candidate for foreign political office, for the purpose of influencing any act or decision of such official in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions and disposition of the company's assets, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA's provisions can be costly and challenging, particularly in countries in which corruption is deemed to be a significant risk and in the life sciences industries, where, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials per se. Certain payments to hospitals in connection with clinical trials and other work have been considered improper payments to government officials and led to FCPA enforcement actions with significant fines and penalties.

Various international trade, export control and sanctions laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. persons in the United States, of products or technology that are controlled for export, as well as restricting our ability to deal with certain persons subject to sanctions. Specifically, certain biological agents, toxins, and related technology are restricted by the United States for export to certain countries for national security reasons and require an export authorization from the U.S. Department of Commerce. U.S. export controls also apply to genetic elements and genetically modified organisms that contain DNA associated with the pathogenicity of these biological materials. There are also a number of foreign parties on the U.S. Specially Designated

Nationals and Blocked Parties List and the Entity List, both of which prohibit certain transactions by U.S. persons or from the U.S. with designated persons. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain product candidates and products outside of the United States, which could limit our growth potential and increase our development costs.

U.S. laws may also restrict our ability to share personal data with certain foreign parties. A final rule (the Data Security Program or DSP Rule) was issued by the U.S. Department of Justice, or DOJ in 2025 to impose restrictions on access to U.S. bulk sensitive personal data and government-related data by certain foreign countries and persons. The DSP Rule prohibits and restricts certain "bulk" data transactions involving China (including Hong Kong and Macau) and other specified "countries of concern" and individuals and entities under their control. To the extent we are subject to these restrictions for cross-border data flows, it could potentially impact our business and restrict our collaboration opportunities.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties for both the company and individuals, as well as possible suspension or debarment from government contracting. The Securities and Exchange Commission, or the SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

***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 harm our business.***

We and our third-party contractors are subject to numerous foreign, federal, state and local 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 involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally 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, including any available insurance.

In addition, our leasing and operation of real property may subject us to liability pursuant to certain of these laws or regulations. Under existing U.S. environmental laws and regulations, current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

We could incur significant costs and liabilities which may adversely affect our financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage and personal injury claims, costs associated with upgrades to our facilities or changes to our operating procedures, or injunctions limiting or altering our operations.

Although we maintain liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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, which are becoming increasingly more stringent, may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***The Company may be exposed to liabilities under the FCPA and Chinese anti-corruption law.***

The Company is subject to the FCPA, and other laws that prohibit improper payments or offers of payments to foreign governments, foreign government officials and political parties by U.S. persons as defined by the statute for purposes of obtaining or retaining businesses. The Company may have agreements with third parties who may make sales in mainland China and the U.S., during the process of which the Company may be exposed to corruption. Activities in Taiwan create the risk of unauthorized payments or offers of payments by an employee, consultant or agent of the Company because these parties are not always subject to the Company's control.

Although the Company believes to date it has complied in all material aspects with the provisions of the FCPA and Chinese anti-corruption law, the existing safeguards and any future improvements may prove to be less than effective and any of the Company's employees, consultants or agents may engage in corruptive conduct for which the Company might be held responsible. Violations of the FCPA or Chinese anti-corruption law may result in severe criminal or civil sanctions against the Company and individuals and therefore could negatively affect the Company's business, operating results and financial condition. In addition, the Taiwanese government may seek to hold the Company liable as a successor for FCPA violations committed by companies in which the Company invests or acquires.

### **Risks Related to Our Reliance on Third Parties**

***We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.***

We do not have the ability to independently conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are dependent on third parties to conduct our clinical trials of our product candidates and any preclinical studies and clinical trials of any other product candidates. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators, laboratories and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these CROs and other third parties are not our employees, and we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. By example, we are required to monitor the activities of third parties undertaking clinical trials on our behalf, but our monitoring may not be able to detect any existing or emerging issues.

We and our CROs, as well as other third parties, including investigators, are required to comply with good clinical practices, or GCP, requirements, which are regulations and guidelines enforced by the FDA for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements or to conduct a trial in accordance with its investigational plan, we or they may be subject to enforcement actions, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our clinical trials comply with GCPs. In addition, our clinical trials must be conducted with product produced under cGMP regulations applicable to the stage of product development and our preclinical trials must be conducted in accordance with good laboratory practices. Our failure or the failure of third parties on whom we rely on to comply with these regulations may require us to stop and/or repeat clinical trials or other studies, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise perform in a substandard manner, or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. We may also have to conduct additional clinical or preclinical trials. If our clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors for whom they may also be conducting clinical trials or other pharmaceutical product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

***Manufacturing pharmaceutical products is complex and subject to product loss for a variety of reasons. We rely on third-party suppliers, including single source suppliers, to manufacture preclinical and clinical supplies of our product candidates and we intend to rely on third parties to produce commercial supplies of any approved product candidate. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.***

We do not have any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, product development purposes, to support regulatory application submissions, as well as for commercial manufacture if any of our product candidates obtain marketing approval. In addition, we expect to contract with analytical laboratories for release and stability testing of our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We may be unable to establish any agreements with third-party manufacturers or do so on favorable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory, compliance and quality assurance;
- reliance on the third party for product development, analytical testing, and data generation to support regulatory applications;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, the issuance of an FDA Form 483 notice or warning letter, or other enforcement action by FDA or other regulatory authority;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our drugs under specified storage conditions and in a timely manner.

We have only limited supply arrangements in place with respect to our product candidates, and these arrangements do not extend to commercial supply. We acquire many key materials on a purchase order basis. As a result, we do not have long-term committed arrangements with respect to our product candidates and other materials. We will need to establish one or more agreements with third parties to develop and scale up the drug manufacturing process, conduct drug testing, and generate data to support a regulatory submission. If we obtain marketing approval for any of our product candidates, we will need to establish an agreement for commercial manufacture with a third party.

In addition, we are dependent on a sole supplier for certain components of our manufacturing process. Even if we are able to replace any raw materials or other materials with an alternative, such alternatives may cost more, result in lower yields or not be as suitable for our purposes. In addition, some of the materials that we use to manufacture our product candidates are complex materials, which may be more difficult to substitute. Therefore, any disruptions arising from our sole suppliers could result in delays and additional regulatory submissions.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. While we would not be manufacturing the products ourselves, we will still be responsible for the ultimate quality of any product or product candidate that we put into distribution. If the FDA determines that our CMOs are not in compliance with FDA laws and regulations, including those governing cGMPs, or if FDA determines that our manufacturing processes are not sufficient, the FDA may deny a new drug application, or NDA, approval until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance. Moreover, our failure, or the failure of our third-party manufacturers and suppliers, to comply with applicable regulations could result in the need to repeat clinical or preclinical trials, sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, 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, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our CMOs are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day-to-day control over the operations of our CMOs, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

In addition, our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of regulatory actions that may be brought against these third parties in the future, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

As we prepare for later-stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our product candidates. We have not yet scaled up the manufacturing process for any of our product candidates. Third party manufacturers may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up or commercial activities. For example, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current CMOs for preclinical and clinical testing cannot perform as agreed, we may be required to replace such CMOs. Additionally, if legal and regulatory requirements change, we may need to seek CMOs outside of certain territories or domestically. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or be able to reach agreement with any alternative manufacturer. Further, our third-party manufacturers may experience manufacturing or shipping difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments, including the ongoing conflicts in Ukraine and the Middle East and increasing tensions in Central and South America, including recent U.S. military operations in Venezuela, or public health epidemics. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that obtain marketing approval on a timely and competitive basis.

***We may enter into collaborations with third parties for the further development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.***

We may seek third-party collaborators for the further development and commercialization of some of our product candidates on a select basis. Our likely collaborators for any future collaboration arrangements include large and mid-size pharmaceutical companies and biotechnology companies. We face significant competition in seeking appropriate collaborators and may not be able to secure an appropriate collaborator. Our ability to reach a definitive agreement for a future collaboration will depend, among other things, upon our assessment of the future collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our future collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our future collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations with future collaborators involving our product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may de-emphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators may not comply with the applicable legal and regulatory requirements;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- if a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If we establish one or more collaborations, all of the risks relating to product development, regulatory approval and commercialization described herein would also apply to the activities of any such future collaborators.

***Changes in United States and China relations, as well as relations with other countries, and/or regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our shares.***

The U.S. government, including the SEC, has made statements and taken certain actions that led to changes to United States and international relations and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with significant China-based operations. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the U.S. or to China, our industry or on us. Any unfavorable government policies on cross-border relations and/or international trade, including increased scrutiny on companies with significant China-based operations and escalation of tensions between China and Taiwan, such as the ongoing step up of military exercises around Taiwan by China, capital controls or tariffs, may affect our ability to raise capital and the market price of our shares.

There have been Congressional legislative proposals to discourage contracting with Chinese companies on the development or manufacturing of pharmaceutical products. For example, the BIOSECURE Act was passed as part of the National Defense Authorization Act for Fiscal Year 2026 and prohibits U.S. government contracts, loans and grants being made to any “biotechnology company of concern” or to any entity that uses biotechnology equipment or services from a “biotechnology company of concern”, including certain entities in China involved in the manufacturing, distribution, provision, or procurement of a biotechnology equipment or service. If our suppliers or our customers were to be designated under the Act, this could potentially harm our business and could severely restrict our ability to purchase services or products from, or otherwise collaborate with “biotechnology companies of concern” without losing the ability to contract with, or otherwise receive funding from, the U.S. government. If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated or if the U.S. or Chinese governments take retaliatory actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our shares.

***International trade policies, including tariffs, sanctions and trade barriers may adversely affect our current and future business, financial condition, results of operations and prospects.***

We operate in a global economy, which includes utilizing third-party suppliers in certain countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. In 2025, the U.S. government announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. For example, in September 2025, the current Presidential Administration announced plans to impose up to 100% tariffs on imported branded or patented pharmaceutical products, subject to certain exceptions. There is substantial uncertainty as to when such tariffs may go into effect and whether such tariffs would apply to the importation of active pharmaceutical ingredients or bulk drug products that are intended for use in clinical trials, and, more generally, about the duration of existing tariffs, implementation of announced tariffs, litigation seeking certain tariff refunds and whether additional tariffs or other retaliatory measures may be imposed, modified or suspended. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

Current or future tariffs will result in increased research and development expenses. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities and international operations, negatively impacting our growth prospects.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain. While we actively monitor these risks, any prolonged economic downturn, escalation in trade

tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this report.

***We are no longer developing our PRMT5 inhibitor, PRT811, and are dependent on our license agreement with Pathos AI, Inc. to develop and commercialize the asset.***

Pursuant to the terms of the license agreement with Pathos (the “Pathos License Agreement”), we granted an exclusive, world-wide license for our selective, brain-penetrant PRMT5 inhibitor, PRT811. Consequently, the commercial success of PRT811 will depend in significant part on the efforts of Pathos. Pathos will pay us milestone payments upon the achievement of specified development and sales milestone events, as well as royalties on sales of the licensed products. If Pathos is unable to commercialize PRT811 or determines not to pursue development or commercialization of PRT811, we will not receive any sales milestones or royalty payments under the Pathos License Agreement.

#### **Risks Related to Commercialization of our Product Candidates**

***The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue potential and ability to achieve profitability will be adversely affected.***

The total addressable market opportunity for any product candidates we may develop will ultimately depend upon, among other things, the diagnosis criteria included in the final labeling for each such product candidate if our product candidates are approved for sale for these indications, acceptance by the medical community, patient access, drug and any related companion diagnostic pricing and their reimbursement. We may initially seek regulatory approval of some of our product candidates as therapies for relapsed or refractory patients. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

***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 any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments, such as existing targeted therapies, chemotherapy, and radiation therapy, are well established in the medical community, and doctors may continue to rely on these treatments. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the acceptance of our product candidates as front-line treatment for various indications;
- the prevalence and severity of any side effects, in particular compared to alternative treatments;
- limitations or warnings, as well as approved indication, contained in the labeling approved for our product candidates by the FDA;
- the size of the target patient population;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the strength of marketing and distribution support;
- publicity for our product candidates and competing products and treatments;

- the existence of distribution and/or use restrictions, such as through a REMS;
- the availability of third-party payor coverage and adequate reimbursement;
- the timing of any marketing approval in relation to other product approvals;
- support from patient advocacy groups; and
- any restrictions on the use of our products together with other medications.

***We currently have no marketing and sales organization and have no experience as a company in commercializing products and we may have to invest significant resources to develop these capabilities. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate revenue.***

We currently have no sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales, marketing and distribution capabilities, either ourselves or through collaboration or other arrangements with third parties.

There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts are expected to be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- our inability to raise financing necessary to build our commercialization infrastructure;
- the inability of sales personnel to obtain access to physicians or educate an adequate number of physicians as to the benefits of our products;
- any sales or marketing personnel's failure to comply with applicable legal or regulatory requirements;
- unfavorable third-party payor coverage and reimbursement in any geography;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales and marketing services, our product revenues and our profitability, if any, are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to market and sell our product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell and market our products effectively or may not do so in a compliant manner, for which we could be held responsible. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any of our product candidates for which we receive marketing approval.

***We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.***

The development and commercialization of pharmaceutical products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide. There are a number of pharmaceutical and biotechnology companies that currently

are pursuing the development of precision oncology therapies optimized to effectively target the key driver mechanisms in cancers with high unmet need.

For our JAK2V617F inhibitor program, competition includes Incyte Corporation, Cogent Biosciences, Eilean Therapeutics, and Atavistik Bio, all of which have publicly disclosed their research and development efforts.

For our KAT6A degrader program, other companies, including Pfizer, Olema Oncology, Menarini Group, BeOne Medicines (f/k/a BeiGene), Ideaya Biosciences, Isosterix and Beijing Konruns Pharmaceutical have publicly disclosed their research and development efforts.

More broadly, several global biopharmaceutical companies have prioritized precision oncology as an area of strategic focus, including but not limited to Amgen Inc., AbbVie Inc., AstraZeneca PLC, Astellas Inc., Bayer AG, Boehringer Ingelheim AG, Bristol Myers Squibb, Inc., Daiichi Sankyo Inc., Eli Lilly and Company, Inc., F. Hoffman-La Roche, Gilead Sciences Inc., GlaxoSmithKline PLC, Johnson & Johnson Services, Inc., Merck & Co. Inc., Novartis AG, and Pfizer Inc. In addition, there are multiple smaller biotech companies focused on discovery and development of precision oncology medicines, including but not limited to Arvinas Inc., Aurigene, Black Diamond Therapeutics, Inc., C4 Therapeutics, Foghorn Therapeutics Inc., Ideaya Biosciences, Kura Oncology, Inc., Kymera Therapeutics Inc., Nuvation Bio Inc., Repare Therapeutics Inc., Revolution Medicines, Inc., Relay Therapeutics, Inc., Tango Therapeutics, Inc., and Zentalis Pharmaceuticals, Inc.

Many of the companies against which we are competing or against which we may compete in the future, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and sales and marketing personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Moreover, we face increased competition from other companies that are using artificial intelligence, some of whom may be able to more quickly and effectively identify and develop novel product candidates compared to us and our business partners, which could impair our ability to compete effectively and have a material adverse effect on our business, results of operations or financial condition.

Furthermore, we also face competition more broadly across the oncology market for cost-effective and reimbursable cancer treatments. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drugs and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of our product candidates that we successfully introduce to the market may pose challenges. In addition, many companies are developing new oncology therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

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 to administer, are less expensive or with a more favorable labeling than our current or future product candidates. Our competitors also may obtain FDA, foreign regulatory authority, or other marketing or regulatory approval for their products more rapidly than any approval we may obtain for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

***Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.***

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways

that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government healthcare programs (e.g., Medicare and Medicaid), private health insurers and other organizations. Third-party payors decide which medications they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, which decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors often, but not always, follow CMS's decisions regarding coverage and reimbursement.

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. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory to cover the costs of research, development, manufacture, sale and distribution. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining coverage and adequate reimbursement for our products may be difficult and can change over time. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

Additionally, we may develop, either by ourselves or with collaborators, companion diagnostic tests for our product candidates for certain indications. We, or our collaborators, if any, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. While we have not yet developed any companion diagnostic test for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates.

There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Our inability to promptly obtain coverage and adequate reimbursement rates from third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

***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 commercialize any products that we may develop. If we cannot successfully defend ourselves against any 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:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- initiation of investigations by regulators;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- diversion of management and scientific resources from our business operations;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Our current product liability insurance coverage for the United States and certain other jurisdictions may not be adequate to cover all liabilities that we may incur. We likely will need to increase our insurance coverage as we expand 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. A successful product liability claim or series of claims brought against us could decrease our cash and adversely affect our business and financial condition.

**Risks Related to Employee Matters and Our Operations**

***Our future success depends on our ability to retain key employees and to attract, retain and motivate qualified personnel and manage our human capital.***

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on the development and management expertise of Kris Vaddi, Ph.D., our founder and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team. We currently do not maintain key person insurance on these individuals. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time.

Our industry has experienced a high rate of turnover in recent years. Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, clinical, regulatory, manufacturing and management skills and experience. We conduct our operations in the greater Delaware area, a region that is home to other pharmaceutical companies as well as many academic and research institutions. We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among pharmaceutical companies, including from companies in other geographic areas hiring remote workers. Many of the other pharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our product candidates and to grow our business and operations as currently contemplated.

***In the future, we may 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 of December 31, 2025, we had 79 full-time employees. We may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, clinical operations, manufacturing, regulatory affairs and, if any of our product candidates 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 resources and the limited experience of our management team in managing a company with such anticipated growth and with developing sales, marketing and distribution infrastructure, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources.

Further, we currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third-party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our clinical trials and the manufacturing of any of our product candidates. We cannot assure you that the services of such third-party contract organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by our vendors or consultants is compromised for any reason, our clinical trials may be extended, delayed, repeated, or terminated, and we may not be able to obtain marketing approval of any of our product candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all.

If we are not able to effectively manage growth and expand our organization, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

***Our employees, clinical trial investigators, CROs, CMOs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, CMOs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, (iv) sexual harassment and other workplace misconduct laws, or (v) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation.

We have adopted a code of conduct applicable to all of our employees, consultants, vendors and other potential commercial partners, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from an alleged failure to comply with these laws or regulations. 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 significant civil and administrative penalties and damages, criminal fines and confinement, disgorgement, exclusion from participation in government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, suspension and debarment from government procurement and non-procurement programs, refusal of orders under existing government contracts, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, 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.

***Our internal information technology systems, or those of our third-party CROs, CMOs, or other vendors, contractors or consultants, may fail or suffer security breaches, cyber-attacks, loss or leakage of data and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.***

We are increasingly dependent upon information technology systems and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party CROs, CMOs, vendors, and other contractors and consultants who have access to our confidential information.

Despite the implementation of reasonable technical, administrative, and physical security measures, our internal information technology systems and those of our third-party CROs, CMOs, vendors and other contractors and consultants (collectively, “Third Parties”) are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, accidents by our employees or third party service providers, natural disasters, terrorism, war and telecommunication and electrical failures.

Our systems, and those of Third Parties, may also experience security breaches from inadvertent or intentional actions by our employees, or from cyber-attacks by malicious third parties including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by insiders, hackers, computer hackers, state sponsored actors, foreign governments, cyber terrorists and other threat actors, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security and operational threats, nor may we be able to implement preventive measures effective against all such threats. The techniques used by threat actors change frequently, may not be recognized until launched and can originate from a wide variety of sources, including insiders, outside groups such as hackers, external service providers, organized crime affiliates, state sponsored actors, terrorist organizations, hostile foreign governments or agencies, or other threat actors. If a disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our Third Parties, or inappropriate disclosure and other compromise of confidential information or impacts to the integrity and availability of data or systems, we could incur liability and reputational damage and the further development and commercialization of our product candidates could be delayed. Any breach, loss or compromise of clinical trial participant personal data may also subject us to civil damages and penalties, under the GDPR (as defined below), HIPAA and other relevant international, state and federal privacy laws, data protection, operational resilience, and cybersecurity. The costs related to significant security breaches, resilience events or disruptions could be material and exceed the limits of the cybersecurity insurance we maintain against such risks. If the information technology systems of our Third Parties become subject to disruptions, resilience events or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Any such incident that leads to loss of integrity or availability, unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could require public notification and/or notification to governmental entities, business partners, suppliers, customers, and individuals, harm our reputation directly, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information or data protection, operational resilience, and cybersecurity, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

***Failure to comply with health and data protection, privacy, cybersecurity, artificial intelligence (AI), and operational resilience laws and regulations (including enacted by governmental authorities in the European Economic Area (“EEA”), Switzerland, and the UK, collectively, “Europe”) could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.***

We and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations (i.e., laws and regulations that address data protection, privacy and data security). In the United States, numerous federal and state

laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, state consumer privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that is subject to privacy, data protection and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-regulated entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including EU Regulation 2016/679, known as the EU General Data Protection Regulation, or along with related data protection, privacy, and cybersecurity laws in Europe, including the UK General Data Protection Regulation, collectively, the “GDPR”), may also apply to health-related and other personal information obtained outside of the United States. The GDPR imposes numerous new requirements for the collection, use and disclosure of personal information and the protection and resiliency of certain network and information systems, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). In addition, the GDPR includes restrictions on cross-border data transfer, which may require ongoing changes to our business operations, implementation of revised legal mechanisms, and other challenges. We are also required to undertake appropriate measures to ensure the confidentiality, availability, and integrity of personal information, which may be challenging considering ever-growing and impactful cyber threats.

The EU GDPR allows European Economic Area supervisory authorities to impose penalties for non-compliance of up to the greater of EUR 20.0 million and 4% of annual worldwide gross revenue of the corporate group in question. (There are similar caps in GBP under the UK GDPR). Supervisory authorities in the EEA and UK may potentially levy such fines directly upon on the non-compliant entity and/or on the parent company of the non-compliant entity. Separate from regulatory enforcement actions, individuals may bring private actions (including potentially group or representative actions) against us. There is no statutory cap in the GDPR on the amount of compensation or the damages which individuals may recover. The GDPR and other international data protection laws will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance. Any failure to do so could have an adverse impact on our business, reputation, financial condition, and results of operations. We may also be subject to additional industry-specific privacy, cybersecurity, data protection, operational and information systems resilience, and AI-related laws in Europe which may subject us to additional similar risks and impacts as under the GDPR.

In addition, data protection requirements and risk are increasing in the United States. The state of California enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the CCPA), including the rights to access, correct, and delete personal information increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA requires covered companies to provide detailed disclosures to consumers about such companies’ data collection, use and sharing practices, provide such consumers ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action for data breaches.

Following California’s lead, other states, including Virginia and Colorado, have adopted similar comprehensive consumer privacy laws. Further, additional states are in the process of enacting or will be considering these laws in the future. These state laws may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Some states, like Washington State, have passed healthcare-specific privacy laws. The My Health My Data Act became effective March 31, 2024 and restricts how entities collect, use, and process “consumer health data,” defined broadly as personal information that is linked or reasonably linkable to a consumer and that identifies the consumer’s health status. While HIPAA-regulated entities may be exempt from the Act, the exemption is based on the data collected and used rather than on the entity’s status as a HIPAA covered entity or business associate. As such, some data may be subject to the Act and HIPAA, while other data may only be subject to HIPAA.

State laws may be more stringent, broader in scope or offer greater individual rights with respect to health-related information or other personal information than HIPAA. Complying with these various state laws and regulations, which may differ from state to state, requires significant resources and may complicate our compliance efforts. Penalties for violation of any of these laws and regulations may include civil and/or criminal penalties these regulatory changes may increase our compliance costs and potential liability, particularly in the event of a data breach.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil, criminal, and administrative penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

***We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Our company is located in Delaware. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party CMOs, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. For example, our operations are concentrated primarily on the east coast of the United States, and any adverse weather event or natural disaster, such as a hurricane or heavy snowstorm, could have a material adverse effect on a substantial portion of our operations. Extreme weather conditions or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical industry are unclear and may heighten or intensify existing risk of natural disasters. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans that we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party CMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or government shutdowns 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, 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, reductions in force, 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 is subject to the impacts of political events, which are inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may slow the time necessary for new drugs 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 FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA and the SEC to timely review and process our submissions, which could have a material adverse effect on our business.

***Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition or results of operations.***

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act, enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Cuts and Jobs Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act, or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Cuts and Jobs Act, the CARES Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

***Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.***

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused losses incurred in taxable years beginning on or prior to December 31, 2017, will carry forward to offset future taxable income, if any, until such unused losses expire. Under the Tax Cuts and Jobs Act, as modified by the CARES Act, unused U.S. federal net operating losses generated in taxable years beginning after December 31, 2017 will not expire and may be carried forward indefinitely but the deductibility of such federal net operating losses (particularly those generated in taxable years beginning after December 31, 2020) in taxable years beginning after December 31, 2020 is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act or the CARES Act. In addition, both our current and our future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code) if we undergo, or have undergone, an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional ownership changes in the future. As a result, our net operating loss carryforwards generated in taxable years beginning on or before December 31, 2017, may expire prior to being used, and the deductibility of our net operating loss carryforwards generated in taxable years beginning after December 31, 2017 in taxable years beginning after December 31, 2020 may be limited, and, if we undergo an ownership change (or if we previously underwent such an ownership change), our ability to use all of our pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

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

From time to time, we may consider strategic transactions, such as acquisitions of companies, businesses or assets and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near term or long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management’s time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;

- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations, systems and personnel of any acquired businesses with our operations, systems and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

***Our portfolio of investments or bank deposits may be subject to market, interest and credit risk that may reduce in value.***

The value of our investments may decline due to increases in interest rates, downgrades of the bonds and other securities included in our commercial money market account portfolio and instability in the global financial markets that reduces the liquidity of securities included in our portfolio. Furthermore, a possible recession, rising inflation, and rising interest rates has and may continue to adversely affect the financial markets in some or all countries worldwide. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks through diversification of our investments and continuous monitoring of our portfolio's overall risk profile, the value of our investments may nevertheless decline.

### **Risks Related to Intellectual Property**

***If we are unable to obtain and maintain sufficient patent protection for our product candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our product candidates successfully may be adversely affected.***

Our success depends in large part on our ability to protect our proprietary technologies that we believe are important to our business, including pursuing, obtaining and maintaining patent protection in the United States and other countries intended to cover the compositions of matter of our product candidates, their methods of use, related technologies and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. If we do not adequately pursue, obtain, maintain, protect or enforce our intellectual property, third parties, including our competitors, may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

To protect our proprietary position, we have currently filed patent applications in the United States related to our product candidates that we consider important to our business, including patent applications relating to compositions of matter covering our compounds, the processes for manufacturing such compounds and use of such compounds in therapies. We have also filed patent applications in foreign jurisdictions relating to our product candidates.

The patent application and approval process is expensive, time-consuming and complex. We may not be able to file, prosecute and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. We also cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, depending on the terms of any future license agreements to which we may become a party, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the patents, covering technology licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Furthermore, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. The standards applied by the United States Patent and Trademark Office, or the USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. In addition, the determination of patent rights with respect to biological and pharmaceutical products commonly involves complex legal and factual questions, which have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Thus, we cannot offer any assurances about

which, if any, patents will issue, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties or whether any issued patents will effectively prevent others from commercializing competing technologies and product candidates. We do not yet have issued patents on all of our product candidates.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until at least one patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the 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. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file or invent (prior to March 16, 2013) any patent application related to our product candidates. In addition, we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, CMOs, hospitals, independent treatment centers, consultants, independent contractors, suppliers, advisors and other third parties; however, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, if third parties have filed patent applications related to our product candidates or technology, we may not be able to obtain our own patent rights to those product candidates or technology.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, revocation, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. 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 rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of exclusivity or in our 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. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, our patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive 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. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors and other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors and other third parties may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors or other third parties may seek to market generic versions or “follow-on” versions of any approved products by submitting abbreviated new drug applications, or ANDAs, or new drug applications under Section 505(b)(2) of the FDCA, respectively, to the FDA during which they may claim that patents owned by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Furthermore, future patents may be subject to a reservation of rights by one or more third parties. For example, to the extent the research resulting in future patent rights or technologies is funded in the future in part by the U.S. government, the government could have certain rights in any resulting patents and technology, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf for non-commercial purposes. If the U.S. government then decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may also 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. The government may also exercise its march-in rights if it determines that action is necessary because we failed to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such government-funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of aforementioned proprietary rights could harm our competitive position, business, financial condition, results of operations, and prospects.

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

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law in September 2011. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. For example, the Leahy-Smith Act allows third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. In addition, the Leahy-Smith Act has transformed the U.S. patent system from a “first-to-invent” system to a “first-to-file” system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The first-to-file provisions, however, only became effective on March 16, 2013. It is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our future collaboration partners’ patent applications and the enforcement or defense of our or our future collaboration partners’ issued patents, all of which could harm our business, results of operations, financial condition and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. 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. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights, trade secrets or other intellectual property. To counter infringement, misappropriation or other violations, we may be required to file infringement, misappropriation or other violation claims, which can be expensive and time consuming and divert the time and attention of our management and business and scientific personnel. In addition, many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their patents or their other intellectual property, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. Similarly, third parties may initiate legal proceedings against us seeking a declaration that certain of our intellectual property is non-infringed, invalid or unenforceable. The outcome of any such proceeding is generally unpredictable.

In any patent infringement proceeding, 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 or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in 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. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our product candidates, we could lose at least a part, and perhaps all, of the patent protection covering such a product candidate. Competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our drugs in one or more foreign countries. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. 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.

Furthermore, third parties may also raise invalidity or unenforceability claims before administrative bodies in the United States or foreign authorities, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of

invalidity and unenforceability is unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or written description. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution of the patent. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our licensors, our patent counsel and the patent examiner were unaware during prosecution. Moreover, it is possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our product candidates. Any such loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects.

***We may not be able to effectively protect or enforce our intellectual property and proprietary rights throughout the world.***

Filing, prosecuting and defending patents with respect to our product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. The requirements for patentability may differ in certain countries, particularly in developing countries. In addition, any future intellectual property license agreements may not always include worldwide rights. Consequently, competitors and other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States and where our ability to enforce our patents to stop infringing activities may be inadequate. These products may compete with our products in such territories and in jurisdictions where we do not have any patent rights or where any future patent claims or other intellectual property or proprietary rights may not be effective or sufficient to prevent them from competing with us, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, our ability to protect and enforce our intellectual property and proprietary rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property and proprietary rights in certain foreign jurisdictions. The legal systems of some countries, including, for example, India, China and other developing countries, do not view favorably the enforcement of patents and other intellectual property or proprietary rights, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property or proprietary rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business, could put our patents, trademarks or other intellectual property and proprietary rights at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, 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. Furthermore, while we intend to protect our intellectual property and proprietary rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property and proprietary rights in such countries may be inadequate.

Further, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, the unitary patent system was introduced in early 2023, which could significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national

patents in the UPC countries. Patents that remain under the jurisdiction of the UPC could be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

***If we are sued for infringing, misappropriating or otherwise violating intellectual property or proprietary rights of third parties, such litigation or disputes could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.***

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. If any third-party patents, patent applications or other proprietary rights are found to cover our product candidates or any related companion diagnostics or their compositions, methods of use or manufacturing, we may be required to pay damages, which could be substantial, and we would not be free to manufacture or market our product candidates or to do so without obtaining a license, which may not be available on commercially reasonable terms, or at all.

We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property or proprietary rights with respect to our product candidates and technologies we use in our business. Our competitors or other third parties may assert infringement claims against us, alleging that our product candidates are covered by their patents. We cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. If a patent holder believes our product candidate infringes its patent rights, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property or proprietary rights with respect to our product candidates, including interference proceedings before the USPTO. Third parties may assert infringement, misappropriation or other claims against us based on existing or future intellectual property or proprietary rights. The outcome of intellectual property litigation and other disputes is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of using or manufacturing products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods of use, manufacturing or other applicable activities either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be successful in doing so. However, proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, or enforceability. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and business and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property or proprietary rights and we are unsuccessful in demonstrating that such intellectual property or proprietary rights are invalid or unenforceable, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby giving our competitors and other third parties access to the same technologies licensed to us. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed such third-party patent rights. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could

materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

***We may be subject to claims by third parties asserting that our employees or consultants or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.***

Some of our employees and consultants are currently or have been previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. These employees and consultants may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such other current or previous employment. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of third parties. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property or personnel or sustain damages. Such intellectual property could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. In addition, such agreements may not be self-executing such that the intellectual property subject to such agreements may not be assigned to us without additional assignments being executed, and we may fail to obtain such assignments. In addition, such agreements may be breached. In addition, we have multiple sponsored research agreements relating to our lead product candidates with various academic institutions. Some of these academic institutions may not have intellectual property assignments or similar agreements with their employees and consultants, which may result in claims by or against us related to ownership of any intellectual property. Accordingly, we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property. 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, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

***Rights to improvements to our product candidates may be held by third parties.***

In the course of testing our product candidates, we have entered into agreements with third parties to conduct clinical testing, which provide that improvements to our product candidates may be owned solely by a party or jointly between the parties. If we determine that rights to such improvements owned solely by a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing the product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby giving our competitors and other third parties access to the same technologies licensed to us. Failure to obtain a license on commercially reasonable terms or at all, or to obtain an exclusive license, could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. If we determine that rights to improvements jointly owned between us and a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such improvements, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

***The term of our patents may be inadequate to protect our competitive position on our 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. Depending upon the timing, duration and other factors relating to any FDA marketing approval we receive for any of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Hatch-Waxman Amendments permit a patent term extension of up to five years beyond the normal expiration of the patent, limited to the approved indication (or any additional indications approved during the period of extension), as compensation for patent term lost to the regulatory review process during which the sponsor was unable to commercially market its new product. A patent term extension cannot extend the total term of a patent beyond 14 years from the date of product approval, only one patent applicable to an approved drug is eligible for the extension, only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available for our patents, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may be denied an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors and other third parties may be able to obtain approval of competing products following our patent expiration and take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent offices, and our patent protection could be reduced or eliminated for noncompliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patent are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent. The USPTO and patent offices in foreign countries require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. In the future, we may rely on licensing partners to pay these fees due to U.S. and non-U.S. patent agencies and to comply with these other requirements with respect to any future licensed patents and patent applications. While 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 a patent or patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors and other third parties might be able to enter the market with similar or identical products of technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

***If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.***

We rely on proprietary know-how and trade secret protection and confidentiality agreements to protect proprietary know-how or trade secrets that are not patentable or that we elect not to patent. We seek to protect our trade secrets and proprietary know-how in part by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, consultants, independent contractors, advisors, CMOs, CROs, hospitals, independent treatment centers, suppliers, collaborators and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary know-how. Additionally, our confidentiality agreements and other contractual protections may not be adequate to protect our intellectual property from unauthorized disclosure, third-party infringement or misappropriation. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our business, financial condition, results of operations and prospects our business and competitive position could be materially harmed.

***Intellectual property rights do not necessarily address all potential threats.***

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

- others may be able to make products similar to any product candidates we may develop or utilize similarly related technologies that are not covered by the claims of the patents that we may license or may own in the future;
- we, or any future license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or any future license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating any of our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

## Risks Related to Our Common Stock

***Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.***

As of December 31, 2025, our executive officers, directors, beneficial owners of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 50% of our common stock and securities convertible into shares of our common stock. The voting power of this group may increase to the extent they convert shares of non-voting common stock or pre-funded warrants that they hold into shares of our common stock.

This concentration of control creates a number of risks. This group of stockholders has the ability to control us through this ownership position and are able to determine all matters requiring stockholder approval. For example, these stockholders are able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction, and other stockholders may find it difficult to replace members of management should they disagree with the manner in which the Company is operated. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

***An active and liquid trading market for our common stock may not be sustained. As a result, you may not be able to resell your shares of common stock at or above the original price paid to acquire such shares.***

An active trading market for our common stock may not be sustained. The market value of our common stock may decrease from the purchase price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the purchase price. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

***Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.***

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the planned and ongoing development of our product candidates or future development programs, including scale-up CMC expenses;
- results of clinical trials, or the addition or termination of future preclinical or clinical trials or funding support by us, or future collaborators or licensing partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in political, economic and general macroeconomic conditions, including but not limited to the ongoing conflicts in Ukraine and the Middle East and increasing tensions in Central and South America, including recent U.S. military operations in Venezuela, supply chain disruptions, rising interest rates, rising inflation rates or a potential recession.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***The market price of our common stock has been, and is likely to be, highly volatile, which could result in substantial losses for purchasers of our common stock.***

From January 1, 2025 to December 31, 2025, the closing price of common stock on the Nasdaq Global Select Market ranged from \$0.61 to \$3.98 per share. We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum stockholders' equity of \$2.5 million and a minimum bid price for our common stock of \$1.00 per share (the "Minimum Bid Price Requirement"), or risk delisting, which would have a material adverse effect on our business. While we have strived to maintain full compliance with applicable Nasdaq listing requirements, previously in March 2025, we received a notice of non-compliance with the Minimum Bid Price Requirement, which we addressed and successfully resolved later that year. In 2025, Nasdaq approved and proposed new rules to suspend and more quickly delist companies that do not comply with the minimum bid price requirement, which could make continued compliance more difficult. The market price of our common stock is likely to continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid. The market price for our common stock may be influenced by many factors, including the other risks described in this section of this Annual Report on Form 10-K and the following:

- enrollment or results of clinical trials of our product candidates, or those of our competitors or our future collaborators, or changes in the development status of our product candidates;
- the failure of any product candidates;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including but not limited to those with development and commercialization partners;
- market conditions in the pharmaceutical and biotechnology sectors;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates and products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- announcement and expectation of additional financing efforts;
- sales or purchases of our common stock by us, insiders or our stockholders;
- general economic, industry and market conditions, or other events or factors, many of which are beyond our control, including but not limited to a potential recession, rising interest rates, and rising inflation.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and adverse impact on the market price of our common stock.

***The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.***

The dual class structure of our common stock may limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock, as well as our pre-funded warrants, may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our restated certificate of incorporation. Consequently, if holders of our non-voting common stock and pre-funded warrants exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our non-voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. For example, on March 6, 2025, the common stock will have 100% of the voting power, but if the holders of non-voting common stock or pre-funded warrants were to convert all of their shares or pre-funded warrants into common stock, the prior common stock would have 56% of the voting power, and the former non-voting common stock and holders of pre-funded warrants would represent 44% of the voting power. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock, non-voting common stock and pre-funded warrants, but 10% or less of our common stock, and are not otherwise an insider of the company, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

***We are a “smaller reporting company” and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.***

We are a “smaller reporting company” under Rule 12b-2 of the Exchange Act. We are therefore entitled to rely on exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, if our revenues remain less than \$100.0 million, and reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10-K as well as our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than \$700.0 million as of the prior June 30 and our annual revenue is less than \$100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250.0 million or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700.0 million as of the prior June 30.

***Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us, which may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.***

Our restated certificate of incorporation and our restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;

- provide that directors may only be removed “for cause” and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of “blank check” preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law, or DGCL, may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

***The exclusive forum provision in our organizational documents may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims.***

Our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision.

This choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or a Federal Forum Provision. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court.

Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions

may limit a stockholders' ability to bring a claim in a judicial forum of their choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees.

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

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

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

#### **General Risk Factors**

***If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.***

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If no or few securities or industry analysts commence coverage of us, the trading price for our common stock could be impacted negatively. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

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

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and the listing requirements of the Nasdaq Global Select Market. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting.

We perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404(a) of the Sarbanes-Oxley Act. This requires that we incur substantial

additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts.

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

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

***We may be subject to securities litigation, which is expensive and could divert management attention.***

The market price of our common stock may be volatile. The stock market in general, and Nasdaq 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. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

***Artificial intelligence technologies ("AI") presents risks and challenges that can impact our business including by posing regulatory, data privacy, data protection, and security risks to our confidential information, proprietary information, and personal data, and also product liability and related risks.***

Issues in the development, implementation, and use of AI, combined with an uncertain regulatory environment (in the United States, European Union, UK, and other countries, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, AI presents risks and challenges that could impact our business. We are in the process of adopting and integrating generative AI tools into our systems for specific use cases reviewed by legal and information security.

Currently, there are no comprehensive federal laws or regulations in the United States that regulate the development of AI or specifically prohibit or restrict their use. However, existing laws, such as HIPAA, may affect how we and our vendors use AI. As well, there are state specific laws in the United States regulating the use of AI in certain applications, and state regulators who have issued their own guidance or rules specific to AI use.

Our vendors may incorporate generative AI tools into their offerings without disclosing this use to us, and the providers of these generative AI tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection (including under HIPAA, state laws, the GDPR and the EU AI Act) and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. The risks arising from the design, development, and use of AI technologies (including AI models, AI systems, and AI tools) across our business and operations (including in connection with finance, data management, and manufacturing activities) include potential data inaccuracies, flawed assumptions, system errors, cybersecurity vulnerabilities, unintended outcomes, and difficulties in integrating AI-driven insights into complex and highly regulated manufacturing and operational environments.

If we, our vendors, or our third-party partners experience an actual or suspected breach, data protection, or privacy or security incident because of the use of generative AI, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed.

Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property, and harms in the physical world, and not just the digital world.

If AI fails to perform as intended by us in our business and operations, produces unreliable or biased outputs, or is perceived as contributing to operational disruptions, quality issues, regulatory noncompliance, or adverse product outcomes, our reputation could be harmed and we could be subject to increased regulatory scrutiny, enforcement action, and regulatory fines (including under HIPAA, state laws, the EU AI Act and GDPR and related laws in the EU/EEA, Switzerland and the

UK), product liability claims, litigation, loss of valuable property and information, or other legal exposures, which could adversely affect our business, reputation, results of operations, and financial condition.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 1C. Cybersecurity****Risk Management and Strategy**

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. These systems are connected to and/or accessed from the Internet and, as a result, are susceptible to cyber-attacks. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. A material cyber-attack on our systems, or any other third-party partners or vendors and their key operating systems, may interrupt our ability to operate our business, damage our reputation, or result in monetary damages.

Prelude has established an Information Security Policy ("IS Policy") in order to establish the high-level direction for properly managing the use, privacy, security, retention, and disposal of Prelude's information and its assets. The IS Policy was prepared using relevant guidance issued and technology standards that are used across various industries. The IS policy applies to all entities who are using Prelude's equipment and resources, including but not limited to: employees, contractors, temporary workers, any third parties with access to the Prelude's resources, and cloud IT providers. Prelude's Head of Information Technology ("IT") also serves as our Information Security Officer and is primarily responsible for implementing and overseeing the IS Policy and identifying, measuring, monitoring, and reporting on key enterprise-wide risks, including cybersecurity risks.

Prelude has also established an Incident Response Policy which includes reporting thresholds and follows standardized identification and authentication practices. If an incident is identified, it is documented by Prelude's Head of IT, who in turn, will report the incident to necessary management members.

**Board Governance and Management**

Prelude's Information Security Officer provides updates on information technology risks, controls and procedure, including Prelude's plans to mitigate cybersecurity risks and respond to data breaches to Prelude's executive leadership team. Our Information Security Officer has over 20 years of experience in information security and possesses the requisite education, skills, experience, and industry certifications expected of an individual assigned to these duties. The Chief Financial Officer and the Chief Legal Officer report to the Chair of the Audit Committee prompt and timely information regarding any significant cybersecurity incident. The significant incident will be reported to the remaining Audit Committee members, as well as ongoing updates regarding any such incident until it has been addressed. Such incidents, as warranted, will be reviewed by the Board of Directors.

The Board of Directors has delegated responsibility for cybersecurity risk oversight to the Audit Committee, which is responsible for (i) regularly reviewing with management significant cybersecurity, privacy, and IT risks or exposures, and the Company's policies and processes with respect to risk assessment and risk management of the same; (ii) regularly reviewing with management an assessment of the steps management has taken to monitor and control such risks; and (iii) regularly reporting to the full Board of Directors on such matters. The Chair of the Audit Committee has expertise in risk management which includes IT and cybersecurity.

Notwithstanding the approach we take to cybersecurity, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us. See Item 1A. "Risk Factors" for a discussion of cybersecurity risks.

**Item 2. Properties.**

Our principal executive offices are located at Chestnut Run Plaza in Wilmington, Delaware. The facility has approximately 81,000 square feet of office and laboratory space that we use for administrative, research and development and other activities. The Chestnut Run Lease commenced in December 2023 and expires in 2037 with three five-year extension options and certain expansion rights.

In 2025, we sublet approximately 20,000 square feet of office space. The sublease began in December 2025 and continues through November 2027 with three one-year extension options. The sublease agreement does not relieve us from

our primary obligations under the Chestnut Run Lease, however, we do expect cash inflows from the agreements to partially offset our future obligations for the duration of the sublease agreement.

We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

**Item 3. Legal Proceedings.**

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. In addition, we may receive letters alleging infringement of patents or other intellectual property rights. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business, operating results, cash flows or financial conditions should such litigation be resolved unfavorably. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

**Item 4. Mine Safety Disclosures.**

Not applicable.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

#### Market Information for Common Stock

Our common stock has been listed on The Nasdaq Global Select Market ("Nasdaq") under the symbol "PRLD" since September 25, 2020. Prior to that there was no public trading market for our common stock.

#### Holders of Record

As of March 6, 2026, there were approximately 20 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

#### Dividend Policy

We currently intend to retain future earnings, if any, for use in operation of our business and to fund future growth. We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

#### Unregistered Sales of Equity Securities

During the year ended December 31, 2025, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

#### Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

### Item 6. [Reserved]

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis contains forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" in this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described below.*

### Overview

Prelude is a precision oncology company built on a foundation of drug discovery excellence to deliver novel precision cancer medicines to underserved patients. By leveraging our core competencies in cancer biology and medicinal chemistry, combined with our clinical development capabilities, we have built an efficient, drug discovery engine and the development expertise necessary to identify compelling biological targets and create new chemical entities, or NCEs, that we advance into clinical trials. We believe our approach could result in better targeted cancer therapies. Our discovery excellence has been supported by our steady progress in advancing a pipeline of novel precision oncology development candidates, alone and with partners. We are working with our partner AbCellera Biologics, Inc. ("AbCellera") on an early-stage discovery program involving potent degraders as payloads for novel antibodies targeting tumor specific antigens. Since our inception in 2016, we have received clearance from the U.S. Food and Drug Administration, or the FDA, for multiple investigational new drug applications, or INDs, and successfully advanced several programs into clinical trials. In addition, we have other differentiated proprietary programs in various stages of preclinical development.

By focusing on developing molecules using broad mechanisms that have multiple links to oncogenic driver pathways in select patients, we have developed a diverse pipeline consisting of multiple distinct programs including kinases, targeted protein degraders, and degrader antibody conjugates ("DAC"). Our pipeline is designed to serve patients with high unmet medical need, where there are limited or no treatment options. We believe we can best address these diseases by harnessing advances in new therapeutic modalities such as targeted protein degradation to develop highly potent and specific agents against clinically validated targets in areas of high unmet need.

Myeloproliferative neoplasms ("MPN") are hematopoietic disorders arising from clonal expansion of hematopoietic stem cells ("HSC") in the bone marrow. Current treatment options for MPN patients offer symptomatic benefit but fail to eliminate disease-initiating clones leading to treatment resistance and progression to secondary acute myeloid leukemia. Therapeutic approaches that can selectively eliminate disease-initiating HSCs and induce molecular remission are an unmet medical need.

Mutations in JAK2, calreticulin ("CALR") and MPL are phenotypic drivers of disease in over 90% of MPN cases. CALR mutations are the second most common driver alteration in MPN, accounting for 20-30% of all cases. Selective expression of mutant CALR on diseased cells but not on normal cells makes CALR a high value target for antibody-directed therapies in MPN.

JAK2V617F is the primary driver mutation responsible for disease progression in the majority of patients living with MPNs. We have discovered novel allosteric inhibitors that bind into the JAK2 JH2 "deep pocket" where the V617F mutation resides. These candidates demonstrate mutant specific inhibition in multiple preclinical models of MPNs. We believe this approach may have the potential to reduce mutant allele burden, slow or even reverse disease progression, and transform treatment outcomes for MPN patients.

PRT12396 our lead, mutant-selective JAK2V617F inhibitor received IND clearance from the U.S. FDA, as announced in February 2026 and we anticipate initiating a Phase 1 study in the second quarter of 2026. The Phase 1 study of PRT12396 is an open-label, multi-center, safety and efficacy study in patients with high-risk polycythemia vera (PV) and intermediate and high-risk myelofibrosis (MF). The primary endpoints of the study include safety, efficacy and PK profile.

As previously announced on November 4, 2025, we entered into an exclusive option agreement (the "Option Agreement") with Incyte Corporation ("Incyte") to acquire our mutative selective JAK2V617F inhibitor program (the "Program") for patients with myeloproliferative neoplasms. Under the Option Agreement, Incyte received an exclusive option to acquire our entire right, title, and interest in and to certain assets, properties, and rights related to the JAK2V617F inhibitor program, including our library of preclinical candidates (collectively, the "Transferred Assets"). We expect to advance the JAK2V617F program to pre-defined milestones. Incyte may elect to exercise its exclusive option during the option period to acquire the program and associated assets from us for \$100 million. As the JAK2V617F program candidates

advance in the clinic, we would be eligible to receive up to \$775 million in additional clinical and regulatory milestones, and single digit royalties on global net sales. Combined, total potential cash payments from the transaction, excluding royalties, could reach up to \$910 million.

We have discovered and are developing a series of selective and orally bioavailable KAT6A selective degraders. We have selected a development candidate and remain on track to file an IND in mid-2026. We believe that selectively degrading KAT6A has the potential for improved efficacy, tolerability and combinability with other agents relative to non-selective inhibitors of KAT6A/B. We recently presented preclinical data supporting this hypothesis at the American Association for Cancer Research Annual Meeting 2025.

Drawing on our expertise in targeted protein degradation, we have discovered and optimized a series of proprietary degrader payloads for use in discovering and developing DACs. We disclosed first data at the 36th EORTC-NCI-AACR Symposium describing preclinical proof-of-concept using a novel, potent SMARCA2/4 dual degrader as a degrader payload conjugated to multiple antibodies. Prelude's SMARCA2/4 dual degraders have shown picomolar potency with potential for increased efficacy, selectivity and improved therapeutic index. DACs have potential to expand the reach of SMARCA degrader technology to cancers without SMARCA4 mutations.

During the second half of 2025, we restructured aspects of our collaboration agreement with AbCellera to allow AbCellera to independently discover, develop and commercialize select undisclosed DACs by providing a non-exclusive license to the Company's degrader payloads among other changes to overall resource allocation, governance, and operational aspects of the collaboration.

In June 2025, at the European Hematology Association, we delivered an oral presentation about our mutated calreticulin ("mCALR") discovery efforts, including the first-in-class CALR-targeted DACs that selectively target mutant CALR expressing cells, with the potential to achieve responses by eliminating MPN clones. These data demonstrate that a CALRxSMARCA2/4 degrader antibody conjugate can selectively degrade SMARCA2/4 in CALR mutant cells and robustly inhibit CALR-mutant cell growth in vitro and in vivo.

On November 4, 2025 we announced that we decided to pause the clinical development of our SMARCA2 degrader program which is comprised of PRT3789 and PRT7732. We then reduced the number of employees to 79 employees as of December 31, 2025.

Since inception, we have devoted substantially all of our resources to developing product and technology rights, conducting research and development, organizing and staffing our company, business planning and raising capital. We have funded our operations primarily through the sale of convertible preferred stock and common stock. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures.

We have incurred recurring losses, the majority of which are attributable to research and development activities, and negative cash flows from operations. Our net loss was \$99.5 million and \$127.2 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of \$683.1 million. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

As of December 31, 2025, we had \$106.4 million in cash, cash equivalents, restricted cash and marketable securities. We expect our existing cash, cash equivalents, restricted cash and marketable securities will enable us to fund our operating expense and capital expenditures into the second quarter of 2027.

### **Regained Nasdaq Compliance**

On March 27, 2025, we received a letter (the "Bid Price Notice") from the Listing Qualifications staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of the Company's common stock for the prior 30 consecutive business days, we were not in compliance with the requirement to maintain a minimum bid price of \$1.00 per share for continued listing on Nasdaq, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). On September 18, 2025, we received a letter from Nasdaq notifying the Company that we had regained compliance with the Minimum Bid Price Requirement and that the matter is now closed.

## Components of Results of Operations

### *Revenue*

To date, we have not recognized any revenue from product sales and we do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, or license agreements with third parties, we may generate revenue in the future from product sales. However, there can be no assurance as to when we will generate such revenue, if at all.

On November 3, 2025, we entered into an Exclusive Option Agreement (the "Option Agreement") with Incyte to acquire our mutative selective JAK2V617F JH2 inhibitor program (the "Program") for patients with myeloproliferative neoplasms.

Under the Option Agreement, Incyte received an exclusive option to acquire our entire right, title, and interest in and to certain assets, properties, and rights related to the Program, including the Company's library of preclinical candidates (collectively, the "Transferred Assets") by way of an Asset Purchase Agreement (the "APA"). We are continuing to advance the Program. At any time commencing on the effective date of the Option Agreement until the later of (a) 30 days after the Company's delivery of the investigational new drug ("IND") ready data package or (b) 15 months after the effective date of the Option Agreement (which 15 month period shall automatically toll for the Company to deliver the IND-ready package but such tolling will not exceed 3 months unless otherwise agreed by the parties) (the "Option Period"), Incyte may elect to exercise its exclusive option to acquire the Program and associated assets from us pursuant to the APA for \$100 million. We received an initial upfront payment of \$35 million in cash from the Option Agreement. Under the APA, we would be eligible to receive up to \$775 million in additional clinical and regulatory milestones, and single digit royalties on global net sales. Combined, total potential cash payments from the transaction could reach up to \$910 million.

Concurrently with the Option Agreement, we entered into a securities purchase agreement with Incyte (the "Securities Purchase Agreement"), pursuant to which Incyte purchased 6,250,000 shares (the "Shares") of our non-voting common stock at a price of \$4.00 per share for gross proceeds of \$25.0 million. Pursuant to the Company's amended and restated certificate of incorporation and subject to the non-voting common stock beneficial ownership limitation, Incyte may elect to convert the Shares into voting shares and in December 2025, Incyte converted 4,372,124 of the Shares into voting shares. Because the Option Agreement and Securities Purchase Agreement were entered into at the same time and negotiated as single commercial package, we accounted for the agreements as a single contract under ASC 606. Based on this exercise, the consideration in the Option Agreement plus any excess consideration paid over the fair value of the equity issued to Incyte is a component of transaction price. In determining the fair value of the common stock issued to Incyte, we considered the closing price of the common stock on the date of the transaction, which was \$3.98 per share, which resulted in a premium paid by Incyte of \$0.02 per share, or \$0.1 million ("Equity Premium"). The remaining \$24.9 million was recorded as an issuance of common stock in stockholders' equity.

We first evaluated whether the arrangement meets the definition of a derivative or contains any embedded derivatives under ASC 815, Derivatives and Hedging. Although the arrangement includes underlying IP-related value, it qualifies for the scope exception as prescribed by ASC 815-10-15-59(b). We next evaluated whether the arrangement represents a funded research and development arrangement under ASC 730, Research and Development. The payments received by Prelude are non-refundable, and there is no contractual requirement, guarantee, or other provision that would require us to repay any of the funds received from Incyte. We also concluded that any presumption that there is an obligation to repay the funds received due to the subsequent related party relationship with Incyte is overcome, and therefore the agreements are not within the scope of ASC 730-20. We also concluded that the agreements are not within the scope of ASC 808, Collaborative Arrangements. We assessed the Option Agreement in accordance with ASC 606, Revenue from Contracts with Customer, and concluded that Incyte is a customer in the context of the Option Agreement. The Option Agreement includes the transfer of the following goods or services: (i) to conduct research and development activities related to the Program and (ii) Incyte's exclusive option to acquire the Company's entire right, title, and interest in and to certain assets, properties, and rights related to the Program. We determined that the exclusive option granted was not a material right and, thus, not a performance obligation.

We determined that the transaction price totaled \$35.1 million, which includes the \$35 million upfront cash payment

received and the equity premium. We allocated \$35.1 million to our performance obligations to conduct research and development activities related to the Program. We will recognize revenue related to the Option Agreement over time as the performance obligations are satisfied using an inputs approach, by applying actual expenses against total budgeted costs. As of December 31, 2025, \$32.4 million of the upfront payment was included in deferred revenue within the balance sheets which we estimate will be recognized within thirteen months from year-end. We recognized \$2.6 million in revenue related to the Option Agreement during the year ended December 31, 2025.

During the third quarter of 2025, we amended our collaboration with AbCellera (the "Amended Agreement") and subsequently in October 2025, further expanded the collaboration (the "Expanded License Agreement"). The Amended Agreement and Expanded License Agreement provided AbCellera a non-exclusive license to use certain of our degrader payloads to independently discover, develop and commercialize a select number of novel DACs against undisclosed antibody targets. The agreements also entailed other changes to overall resource allocation and collaboration governance. For the newly licensed DAC programs, AbCellera received world-wide rights to lead and fully control the licensed programs at its sole cost and expense and we are not responsible for any additional financial responsibilities or go forward development costs associated with those programs. We received an upfront non-refundable payment from AbCellera of \$6.5 million upon signing the Amended Agreement and an upfront non-refundable payment of \$6 million upon signing of the Expanded License Agreement. For the additional licensed DACs, we are also eligible to receive customary downstream milestones and single digit royalties on future product sales. The original collaboration agreement with AbCellera, whereunder the companies can jointly discover, develop, and commercialize novel DACs for up to five programs remains in effect.

We assessed the Amended Agreement signed in accordance with ASC 606, Revenue from Contracts with Customer, and concluded that AbCellera is a customer in the context of the Amended Agreement. The Amended Agreement required us to transfer certain intellectual property and related know-how to AbCellera which represented the only performance obligation in the Amended Agreement and was satisfied at a point in time, when the intellectual property and related know-how were transferred to AbCellera during the third quarter of 2025.

We assessed the Expanded Agreement signed in accordance with ASC 606 and concluded that AbCellera is a customer in the context of the Expanded Agreement. We determined the promised goods and services included discovering degrader payloads and granting the licenses to the payloads to AbCellera for them to use to research, develop, and commercialize products related to each of the initial targets mutually agreed upon. Each of these licenses is distinct, as AbCellera can derive benefit from each license independent of any other payload. Each performance obligation will be fully satisfied at the point in time when the license is transferred to AbCellera. For the year ended December 31, 2025, we recognized revenue \$3.0 million in the statement of operations related to the Expanded Agreement. We estimate the remaining performance obligations will be completed in the second half of 2026.

In May 2024, the Company and Pathos AI, Inc. ("Pathos") entered into a license agreement under which we granted to Pathos an exclusive, sublicensable, world-wide license to its selective, brain-penetrant PRMT5 inhibitor, PRT811. Under the terms of the license agreement, we received a \$3.0 million upfront, non-refundable payment. The agreement also included a near term \$4.0 million payment upon the earlier of 180 days following the effective date of the license agreement or the execution of a quality agreement between the parties pursuant to which we transferred title to certain quantities of Active Pharmaceutical Ingredient ("API"). In addition, we may receive potential developmental milestone payments up to \$37.0 million, potential sales milestone payments up to \$100 million and a range of high single-digit to low double-digit royalties on PRT811 global net sales.

We assessed the license agreement with Pathos in accordance with ASC Topic 606, Revenue from Contracts with Customers, and concluded that Pathos is a customer. We evaluated all of the promised goods or services within the contract and determined which goods and services were separate performance obligations. We determined that the exclusive license and transfer of related know-how and materials represent one combined performance obligation. The execution of a quality agreement pursuant to which we transferred title to certain API was identified as a separate performance obligation. Both performance obligations were satisfied in 2024.

### ***Operating Expenses***

#### *Research and Development Expenses*

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred, including:

- expenses incurred to conduct the necessary discovery-stage laboratory work, preclinical studies and clinical trials required to obtain regulatory approval;
- personnel expenses, including salaries, benefits and stock-based compensation expense for our employees engaged in research and development functions;
- costs of funding research performed by third parties, including pursuant to agreements with clinical research organizations ("CROs"), that conduct our clinical trials, as well as investigative sites, consultants and CROs that conduct our preclinical and nonclinical studies;
- expenses incurred under agreements with contract manufacturing organizations ("CMOs") including manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- fees paid to consultants who assist with research and development activities;
- expenses related to regulatory activities, including filing fees paid to regulatory agencies; and
- allocated expenses for facility costs, including rent, utilities, depreciation and maintenance.

We track outsourced development costs and other external research and development costs to specific product candidates on a program-by-program basis, fees paid to CROs, CMOs and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. However, we do not track our internal research and development expenses on a program-by-program basis as they primarily relate to compensation, early research and other costs which are deployed across multiple projects under development.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect to continue to incur research and development expenses over the next several years related to personnel costs, including stock-based compensation, clinical trials, including later-stage clinical trials, for current and future product candidates and preparing regulatory filings for our product candidates.

#### *General and Administrative Expenses*

General and administrative expenses consist primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for employees and consultants in executive, finance and accounting, legal, operations support, information technology and human resource functions. General and administrative expense also includes corporate facility costs not otherwise included in research and development expense, including rent, utilities, depreciation and maintenance, as well as legal fees related to intellectual property and corporate matters and fees for accounting and consulting services.

We expect to continue to incur general and administrative expense in the future to support our continued research and development activities and potential commercialization efforts. These expenses will likely include costs related to personnel and fees to outside consultants and legal support, among other expenses. The costs associated with being a public company include expenses related to services associated with maintaining compliance with the requirements of Nasdaq and the Securities and Exchange Commission ("SEC") insurance and investor relations costs. If any of our current or future product candidates obtains U.S. regulatory approval, we expect that we would incur significantly increased expenses associated with building a sales and marketing team.

#### *Other Income, Net*

Other income, net consists primarily of interest earned on our cash equivalents and marketable securities, research and development tax credits, and grant income received from the State of Delaware.

#### *Income Taxes*

Since our inception, we have not recorded any income tax benefits for the net operating losses ("NOLs") we have incurred or for our research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our NOLs and tax credits will not be realized.

## Results of Operations

### Comparison of the Years Ended December 31, 2025 and 2024

The following table sets forth our results of operations for the years ended December 31, 2025 and 2024.

(in thousands)	Year ended December 31,		Change
	2025	2024	
Revenue	\$ 12,140	\$ 7,000	\$ 5,140
Operating expenses:			
Research and development	94,300	117,995	(23,695)
General and administrative	22,406	28,719	(6,313)
Total operating expenses	116,706	146,714	(30,008)
Loss from operations	(104,566)	(139,714)	35,148
Other income, net	5,068	12,541	(7,473)
Net loss	\$ (99,498)	\$ (127,173)	\$ 27,675

#### Revenue

Revenue increased by \$5.1 million to \$12.1 million for the year ended December 31, 2025 from \$7.0 million for the year ended December 31, 2024. Revenue for the year ended December 31, 2025 included \$2.6 million related to our Option Agreement and \$9.5 million from our Amended Agreement and Expanded Agreement. Revenue for the year ended December 31, 2024, was solely related to our license agreement with Pathos.

#### Research and Development Expenses

Research and development expenses decreased by \$23.7 million to \$94.3 million for the year ended December 31, 2025 from \$118.0 million for the year ended December 31, 2024. Included in research and development expenses for the year ended December 31, 2025, was \$6.9 million of non-cash expense related to stock-based compensation expense, including employee stock options, compared to \$12.1 million for the year ended December 31, 2024. Along with the decrease in stock-based compensation expense, research and development expenses decreased due to a decrease in expense related to our discontinued clinical trials, primarily PRT3789 and PRT2527. Research and development expenses may fluctuate from period to period depending upon the stage of certain projects and the level of preclinical and clinical trial-related activities.

Research and development expenses by program are summarized in the table below. Included in Other are programs such as PRT2527, PRT1419, and PRT3645.

(in thousands)	Year ended December 31,	
	2025	2024
PRT3789	\$ 13,461	\$ 20,173
PRT7732	9,145	9,195
Discovery programs, including JAK2V617F, KAT6A and mCALR	12,129	13,856
Other	3,475	12,940
General costs, including personnel related	56,090	61,831
	\$ 94,300	\$ 117,995

#### General and Administrative Expenses

General and administrative expenses decreased by \$6.3 million to \$22.4 million for the year ended December 31, 2025 from \$28.7 million for the year ended December 31, 2024. Included in the general and administrative expenses for the year ended December 31, 2025 was \$5.0 million of non-cash expense related to stock-based compensation expense, including employee stock options, as compared to \$9.2 million for the same period in 2024. The decrease in general and administrative expense was primarily due to a decrease in stock-based compensation along with a decrease in employee related expenses.

#### Other Income, net

Other income, net decreased by \$7.5 million to \$5.1 million for the year ended December 31, 2025 from \$12.5 million for the year ended December 31, 2024, primarily due to lower income earned on our investments due to lower balances and lower research and development tax credits received in 2025.

## Liquidity and Capital Resources

### *Overview*

Since our inception, we have not recognized any product revenue and have incurred operating losses and negative cash flows from our operations. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. Since our inception, we have funded our operations through the sale of convertible preferred stock, common stock, and pre-funded warrants. As of December 31, 2025, we had \$106.4 million in cash, cash equivalents, restricted cash and marketable securities and had an accumulated deficit of \$683.1 million. We expect our existing cash, cash equivalents, and marketable securities will enable us to fund our operating expense and capital expenditures into the second quarter of 2027.

As described in Note 8, in November 2025 the Company received \$60 million in capital, comprised of an initial payment of \$35 million in cash plus a \$25 million equity investment, from Incyte Corporation. We also received an upfront non-refundable payment from AbCellera of \$6.5 million upon signing the Amended Agreement and an upfront non-refundable payment of \$6.0 million upon signing of the Expanded License Agreement.

### *Funding Requirements*

Our primary use of cash is to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

We will need to raise substantial additional capital to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we plan to finance our operations through the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing as and when needed to finance our operations on terms acceptable to us or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to secure adequate additional funding, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, timing, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs of manufacturing our product candidates for clinical trials and in preparation for marketing approval and commercialization;
- the extent to which we enter into collaborations or other arrangements with additional third parties in order to further develop our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the costs and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;
- expenses needed to attract and retain skilled personnel;
- costs associated with being a public company;
- the costs required to scale up our clinical, regulatory and manufacturing capabilities;
- the costs of future commercialization activities, if any, including establishing sales, marketing, manufacturing and distribution capabilities, for any of our product candidates for which we receive marketing approval; and
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval.

We will need additional funds to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and business development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

In May 2024, the Company filed a shelf registration statement (the "2024 Shelf Registration Statement") with the SEC for the issuance of common stock, preferred stock, debt securities, warrants, subscription rights and units up to an aggregate amount of \$400.0 million. The 2024 Shelf Registration statement was declared effective on June 10, 2024. As of December 31, 2025, there was \$400.0 million remaining under the 2024 Shelf Registration Statement.

In March 2023, in connection with filing a prospectus supplement to our 2021 Shelf Registration Statement, we entered into an Open Market Sales Agreement (the "Sales Agreement") with Jefferies LLC, as the sales agent, pursuant to which we may offer and sell shares of our common stock having an aggregate offering amount of up to \$75.0 million. We will pay Jefferies LLC a commission rate of up to 3.0% of the aggregate gross proceeds from the sale of any shares of common stock pursuant to the Sales Agreement. In November 2024, the 2021 Shelf Registration Statement expired with respect to the shares to be sold under the Sales Agreement. Accordingly, we expect to file a prospectus supplement to the 2024 Shelf Registration Statement in order to continue to allow us to access the Sales Agreement. We have \$75.0 million remaining under the Sales Agreement as of December 31, 2025.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

### **Cash Flows**

The following table shows a summary of our cash flows for the periods indicated:

(in thousands)	Years ended December 31,	
	2025	2024
Net cash used in operating activities	\$ (56,302)	\$ (102,888)
Net cash provided by investing activities	53,459	90,191
Net cash provided by (used in) financing activities	24,816	(120)
Net increase (decrease) in cash and cash equivalents	\$ 21,973	\$ (12,817)

### **Operating Activities**

During the year ended December 31, 2025, we used \$56.3 million of cash in operating activities. Cash used in operating activities reflected our net loss of \$99.5 million, partially offset by noncash charges of \$14.8 million, which consisted primarily of \$11.9 million in stock-based compensation, along with a \$28.4 million net increase in our operating assets and liabilities, which related primarily to an increase in deferred revenue. The primary use of cash was to fund our operations related to the development of our product candidates.

During the year ended December 31, 2024, we used \$102.9 million of cash in operating activities. Cash used in operating activities reflected our net loss of \$127.2 million, partially offset by noncash charges of \$20.1 million, which consisted primarily of \$21.3 million in stock-based compensation, along with a \$4.2 million net decrease in our operating assets and liabilities. The primary use of cash was to fund our operations related to the development of our product candidates.

### *Investing Activities*

During the year ended December 31, 2025, net cash provided by investing activities of \$53.5 million consisted primarily of \$154.4 million in proceeds from maturities of marketable securities, partially offset by \$100.9 million in purchases of marketable securities. During the year ended December 31, 2024, net cash provided by investing activities of \$90.2 million consisted primarily of \$143.6 million in proceeds from maturities of marketable securities, partially offset by \$52.7 million in purchases of marketable securities.

### *Financing Activities*

During the year ended December 31, 2025, net cash provided by financing activities was primarily attributable to the gross proceeds of \$25.0 million received from the sale of our common stock under the securities purchase agreement with Incyte, partially offset by payments of offering costs related to the securities purchase agreement and principal payments on our finance lease. During the year ended December 31, 2024, net cash used by financing activities was primarily for principal payments on our finance lease and the payment of offering costs related to the shelf registration statement, partially offset by proceeds received from the issuance of common stock under the employee stock purchase plan.

### **Contractual obligations and other commitments**

We have one operating lease for office and lab space (the Chestnut Run Lease). Our leased facility includes approximately 81,000 rentable square feet and has approximately 11 years remaining along with three five-year extension options and certain expansion rights. The gross obligation for our operating lease over the next twelve months is \$3.0 million, and we expect to make total lease payments of \$38.7 million from January 2026 through May 2037.

During 2025, we entered a sublease agreement which began in December 2025 for approximately 20,000 square feet of office space and has a duration of two years. The sublease agreement does not relieve us from our primary obligations under the Chestnut Run Lease, however, we do expect cash inflows from the agreements to partially offset our future obligations for the duration of the sublease agreement. The aggregate estimated rent payments due over the initial term of the sublease is approximately \$1.2 million.

See Note 8 to our financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

### **Critical Accounting Estimates**

This management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. On an ongoing basis, management evaluates its estimates and judgments. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We regard an accounting estimate or assumption underlying our financial statements as a "critical accounting estimate" if:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and
- the impact of the estimates and assumptions on financial condition or operating performance is material.

While our significant accounting policies are described in more detail in Note 3 (Summary of Significant Accounting Policies) to our audited financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies are the most critical to the judgments and estimates used in the preparation of our financial statements.

### ***Revenue Recognition***

The Company has no product revenue to date and recognizes revenue from our option, collaboration, and license agreements. The Company recognizes revenue under Accounting Standard Codification 606 – Revenue from Contracts with Customers. Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. Our revenue recognition analysis consists of the following steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations; and (v) recognition of revenue as we satisfy each performance obligation.

We apply significant judgment when we determine which goods and services are separate performance obligations, allocate the transaction price, and determine when a performance obligation has been satisfied. We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligations when (or as) the performance obligations are satisfied. We recognize a liability when we have received payment but have not yet satisfied the related performance obligations.

### ***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred.

We accrue an expense for preclinical studies and clinical trial activities performed by our CROs and vendors based upon estimates of the proportion of work completed. We determine the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with our internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including our clinical development plan.

We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Nonrefundable advance payments for goods and services, including fees for clinical trial expenses, process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

### ***Share-Based Compensation***

We recognize compensation costs related to share-based awards granted to employees and directors, including stock options and vesting restricted stock, based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value of stock options, and the resulting stock-based compensation, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

We estimate the fair value of stock options using the Black-Scholes option-pricing model, which requires assumptions, including volatility, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options, and our expected dividend yield. Certain assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future.

These subjective assumptions are estimated as follows:

*Expected volatility*— As a public company we have computed the historical volatility of our own stock price and will continue to use the average volatility for comparable publicly traded biotechnology companies until we have ample trading history of our own stock commensurate with the estimated expected term of our options. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.

*Expected Term* — The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. The simplified method deems the expected term to be the midpoint between the vesting date and the contractual life of the stock-based awards.

### **Smaller Reporting Company Status**

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

### **Recent Accounting Pronouncements**

See Note 3 to our financial statements included elsewhere in this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our financial statements.

### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

### **Item 8. Financial Statements and Supplementary Data.**

## INDEX TO FINANCIAL STATEMENTS

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Prelude Therapeutics Incorporated

### Opinion on the Financial Statements

We have audited the accompanying balance sheets of Prelude Therapeutics Incorporated (the Company) as of December 31, 2025 and 2024, the related statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

### Basis for Opinion

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

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

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

### Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

#### *Accrued and Prepaid Research and Development Expenses*

##### *Description of the Matter*

As described in Note 3 to the financial statements, the Company records research and development expenses as incurred. The Company records accrued and prepaid expenses for preclinical studies and clinical trial activities pursuant to contracts with third-party vendors that perform these services on its behalf. At December 31, 2025, the Company recorded accrued and prepaid research and development expenses, which are included in accrued expenses and other current liabilities and prepaid expenses and other current assets, respectively, on the balance sheet. These amounts were recorded at the balance sheet date based upon estimates of the services provided but not yet invoiced, or services paid for but not yet provided. Management determined the estimates by reviewing contracts, vendor agreements and purchase orders with the third parties, and through discussions with internal clinical personnel and the third-party vendors as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services.

Auditing the Company's accrued and prepaid research and development expenses is challenging because of the judgment applied by management to determine the progress or stage of completion of the activities under the Company's research and development agreements and the cost and extent of work performed during the reporting period by contracted third-party vendors.

*How We Addressed  
the Matter in Our  
Audit*

To test the accrued and prepaid research and development expenses, our audit procedures included, among others, reviewing a sample of contracts, vendor agreements and purchase orders with third-party vendors to corroborate key financial and contractual terms. To assess the completeness and accuracy of the inputs used by management in calculating the accrued and prepaid research and development expenses, our audit procedures included, on a sample basis, confirming certain data directly with third parties and corroborating the progress of research and development activities with the Company's clinical personnel. To evaluate the completeness of the accruals and existence of the prepaids, we also examined subsequent invoices from the third parties and cash disbursements to the third parties, to the extent such invoices were received, or payments were made, prior to the date that the financial statements were issued.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

Philadelphia, Pennsylvania

March 10, 2026

**PRELUDE THERAPEUTICS INCORPORATED**

**BALANCE SHEETS**

(in thousands, except share and per share data)	December 31,	
	2025	2024
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 35,256	\$ 12,474
Marketable securities	67,958	121,140
Prepaid expenses and other current assets	2,478	2,281
Total current assets	105,692	135,895
Restricted cash	3,235	4,044
Property and equipment, net	5,113	6,767
Right-of-use asset	27,165	28,699
Prepaid expenses and other non-current assets	110	110
Total assets	\$ 141,315	\$ 175,515
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 3,983	\$ 7,732
Accrued expenses and other current liabilities	12,533	15,209
Deferred revenue	33,734	—
Operating lease liability	2,744	2,492
Finance lease liability	—	208
Total current liabilities	52,994	25,641
Deferred revenue, net of current portion	1,798	—
Other liabilities	2,841	3,090
Operating lease liability	15,045	15,325
Total liabilities	72,678	44,056
Commitments (note 8)		
Stockholders' equity:		
Voting common stock, \$0.0001 par value: 487,149,741 shares authorized; 48,225,493 and 42,298,859 shares issued and outstanding at December 31, 2025 and 2024, respectively	5	4
Non-voting common stock, \$0.0001 par value: 112,850,259 and 12,850,259 shares authorized at December 31, 2025 and 2024, respectively; 14,728,135 and 12,850,259 shares issued and outstanding at December 31, 2025 and 2024, respectively	1	1
Additional paid-in capital	751,684	714,982
Accumulated other comprehensive income	8	35
Accumulated deficit	(683,061)	(583,563)
Total stockholders' equity	68,637	131,459
Total liabilities and stockholders' equity	\$ 141,315	\$ 175,515

See accompanying notes to financial statements.

**PRELUDE THERAPEUTICS INCORPORATED**

**STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

(in thousands, except share and per share data)	Year ended December 31,	
	2025	2024
Revenue	\$ 12,140	\$ 7,000
Operating expenses:		
Research and development	94,300	117,995
General and administrative	22,406	28,719
Total operating expenses	\$ 116,706	\$ 146,714
Loss from operations	(104,566)	(139,714)
Other income, net	5,068	12,541
Net loss	\$ (99,498)	\$ (127,173)
Per share information:		
Net loss per share of common stock, basic and diluted	\$ (1.29)	\$ (1.68)
Weighted average common shares outstanding, basic and diluted	76,956,194	75,805,840
Comprehensive loss		
Net loss	\$ (99,498)	\$ (127,173)
Unrealized (loss) on marketable securities, net of tax	(27)	(188)
Comprehensive loss	\$ (99,525)	\$ (127,361)

See accompanying notes to financial statements.

**PRELUDE THERAPEUTICS INCORPORATED**  
**STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**

	Voting common stock		Non-voting common stock		Additional paid-in capital	Accumulated Other Comprehensive Income (Loss)	Accumulated deficit	Total
	Shares	Amount	Shares	Amount				
(in thousands, except shares)								
<b>Balance at December 31, 2024</b>	42,298,859	\$ 4	12,850,259	\$ 1	\$ 714,982	\$ 35	\$ (583,563)	\$ 131,459
Issuance of common stock upon exercise of stock options & vesting of RSUs, net of 13,924 shares withheld for employee taxes	35,891	—	—	—	(1)	—	—	(1)
Issuance of common stock under ESPP	218,792	—	—	—	150	—	—	150
Issuance of common stock in connection with the Securities Purchase Agreement, net of \$234 thousand in offering costs	4,372,124	1	1,877,876	—	24,640	—	—	24,641
Issuance of common stock upon exercise of prefunded warrants, net of 173 shares withheld for exercise price	1,299,827	—	—	—	—	—	—	—
Unrealized loss on marketable securities, net of tax	—	—	—	—	—	(27)	—	(27)
Stock-based compensation expense	—	—	—	—	11,913	—	—	11,913
Net loss	—	—	—	—	—	—	(99,498)	(99,498)
<b>Balance at December 31, 2025</b>	<u>48,225,493</u>	<u>\$ 5</u>	<u>14,728,135</u>	<u>\$ 1</u>	<u>\$ 751,684</u>	<u>\$ 8</u>	<u>\$ (683,061)</u>	<u>\$ 68,637</u>

	Voting common stock		Non-voting common stock		Additional paid-in capital	Accumulated Other Comprehensive Income (Loss)	Accumulated deficit	Total
	Shares	Amount	Shares	Amount				
(in thousands, except shares)								
<b>Balance at January 1, 2024</b>	42,063,995	\$ 4	12,850,259	\$ 1	\$ 693,252	\$ 223	\$ (456,390)	\$ 237,090
Issuance of common stock upon exercise of stock options & vesting of RSUs, net of 15,455 shares withheld for employee taxes	42,000	—	—	—	6	—	—	6
Issuance of common stock under ESPP	192,864	—	—	—	379	—	—	379
Unrealized loss on marketable securities, net of tax	—	—	—	—	—	(188)	—	(188)
Stock-based compensation expense	—	—	—	—	21,345	—	—	21,345
Net loss	—	—	—	—	—	—	(127,173)	(127,173)
<b>Balance at December 31, 2024</b>	<u>42,298,859</u>	<u>\$ 4</u>	<u>12,850,259</u>	<u>\$ 1</u>	<u>\$ 714,982</u>	<u>\$ 35</u>	<u>\$ (583,563)</u>	<u>\$ 131,459</u>

See accompanying notes to financial statements.

**PRELUDE THERAPEUTICS INCORPORATED**

**STATEMENTS OF CASH FLOWS**

(in thousands)	Year ended December 31,	
	2025	2024
Cash flows used in operating activities:		
Net loss	\$ (99,498)	\$ (127,173)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,711	1,772
Noncash lease expense	1,534	1,591
Stock-based compensation	11,913	21,345
Amortization of premium and discount on marketable securities, net	(371)	(4,639)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(197)	373
Accounts payable	(3,918)	3,305
Accrued expenses and other liabilities	(2,980)	(808)
Deferred revenue	35,532	—
Long-term prepaid expenses and other long-term assets	—	295
Operating lease liabilities	(28)	1,051
Net cash used in operating activities	(56,302)	(102,888)
Cash flows provided by investing activities:		
Purchases of marketable securities	(100,866)	(52,694)
Proceeds from maturities of marketable securities	154,392	143,649
Purchases of property and equipment	(67)	(764)
Net cash provided by investing activities	53,459	90,191
Cash flows provided by (used in) financing activities:		
Proceeds from issuance of common stock in connection with the Securities Purchase Agreement	24,875	—
Payment of offering costs	—	(110)
Proceeds from issuance of common stock in connection with the exercise of stock options	16	60
Proceeds from the issuance of common stock under ESPP	150	379
Payment of withholding taxes related to stock-based compensation to employees	(17)	(54)
Principal payments on finance lease	(208)	(395)
Net cash provided by (used in) financing activities	24,816	(120)
Net increase (decrease) in cash and cash equivalents	21,973	(12,817)
Cash, cash equivalents and restricted cash at beginning of year	16,518	29,335
Cash, cash equivalents and restricted cash at end of year	\$ 38,491	\$ 16,518
Supplemental disclosures:		
Property and equipment in accounts payable	\$ —	\$ 10
Unrealized loss on marketable securities	\$ (27)	\$ (188)
Offering costs in accounts payable and accrued expenses and other current liabilities	\$ 234	\$ —

See accompanying notes to financial statements.

## PRELUDE THERAPEUTICS INCORPORATED

### NOTES TO FINANCIAL STATEMENTS

#### 1. Nature of Operations

Prelude Therapeutics Incorporated (the “Company”) is a precision oncology company built on a foundation of drug discovery excellence to deliver novel precision cancer medicines to underserved patients. Since beginning operations in 2016, the Company has devoted substantially all its efforts to research and development, conducting preclinical and clinical studies, recruiting management and technical staff, administration, and raising capital.

#### 2. Risks and Liquidity

The Company faces a number of risks common to early-stage companies in the biotechnology industry. Principal among these risks are the uncertainties in the development process, development of the same or similar technological innovations by competitors, protection of proprietary technology, dependence on key personnel, compliance with government regulations and approval requirements, and the need to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance-reporting capabilities. There can be no assurance that the Company’s research and development will be successfully completed, adequate protection for the Company’s technology will be obtained, any products developed will obtain necessary government regulatory approval, or any approved products will be commercially viable. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies.

Since its inception, the Company has incurred operating losses and had an accumulated deficit of \$683.1 million as of December 31, 2025. The Company has no product revenue to date and devotes its efforts to research and development. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates currently in development.

At December 31, 2025, the Company had cash, cash equivalents, restricted cash and marketable securities totaling \$106.4 million and the Company believes these funds will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next twelve months from the filing date of this Annual Report on Form 10-K.

To fund its operating expenses and capital expenditure requirements after that date, the Company plans to seek additional funding through public or private equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into strategic alliances or other arrangements on favorable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company’s stockholders. If the Company is unable to obtain funding, it could be required to delay, reduce or eliminate research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect its business prospects.

**PRELUDE THERAPEUTICS INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS — Continued**

**3. Summary of Significant Accounting Policies**

***Basis of Presentation***

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

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and contingent liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Estimates and assumptions are periodically reviewed, and the effects of the revisions are reflected in the accompanying financial statements in the period they are determined to be necessary. The most significant estimate relates to accrued clinical trial expenses.

***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash, cash equivalents, and marketable securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant credit risk beyond the normal credit risk associated with commercial banking relationships.

***Segment Information***

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company’s chief operating decision maker (“CODM”) is its Chief Executive Officer. The Company views and manages its operations as a single operating segment. See Note 9 - Segments for further details.

***Fair Value of Financial Instruments***

Management believes the carrying amounts of the Company’s financial instruments, including cash, restricted cash, accounts payable, and accrued expenses, approximate fair value due to the short-term nature of these instruments.

***Cash, Cash Equivalents and Restricted cash***

The Company’s cash equivalents include short-term highly liquid investments with an original maturity of 90 days or less when purchased and are carried at fair value in the accompanying balance sheets.

Restricted cash comprises a letter of credit for the benefit of the landlord in connection with the Company’s Chestnut Run Lease. See Note 8 - Commitments for further details.

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the balance sheet that total to the amounts shown in the statement of cash flows:

(in thousands)	December 31,	
	2025	2024
Cash and cash equivalents	\$ 35,256	\$ 12,474
Restricted cash	3,235	4,044
Total cash, cash equivalents, and restricted cash shown in statement of cash flows	\$ 38,491	\$ 16,518

**PRELUDE THERAPEUTICS INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS — Continued**

***Marketable Securities***

The Company's marketable securities consist of investments in corporate debt securities and United States ("U.S") government debt securities that are classified as available-for-sale. The securities are carried at fair value with the unrealized gains and losses, net of tax, included in accumulated other comprehensive income (loss), a component of stockholders' equity. Realized gains and losses as well as credit losses, if any, on marketable securities are included in the Company's statements of operations. The Company classifies marketable securities that are available for use in current operations as current assets on the balance sheets.

***Property and Equipment***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation expense is recognized using the straight-line method over the estimated useful life of the asset, ranging from 5-7 years as follows:

Fixed Asset Type	<u>Estimated useful life</u>
Lab equipment	5 years
IT equipment	5 years
Furniture and fixtures	7 years

Leasehold improvements are amortized over the shorter of the estimated useful life of the assets or the remaining lease term.

Expenditures for repairs and maintenance of assets are charged to expense as incurred, while major betterments are capitalized. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in the statements of operations.

The Company reviews long-lived assets, such as property and equipment, for impairment when events or changes in circumstances indicate the carrying amount of the assets may not be recoverable. If indicators of impairment are present, the assets are tested for recoverability by comparing the carrying amount of the assets to the related estimated future undiscounted cash flows that the assets are expected to generate. If the expected cash flows are less than the carrying value of the asset, then the asset is considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted future cash flows.

***Leases***

The Company accounts for leases in accordance with ASC Topic 842, *Leases*. The Company's lease for office and laboratory space located in Wilmington, DE is classified as an operating lease. The lease results in an operating right-of-use (ROU) asset, a current operating lease liability, and a non-current operating lease liability in the balance sheet and has a remaining lease term of approximately 11 years. Leases with a term of 12 months or less are considered short-term and a ROU asset and lease obligation are not recognized.

ROU assets represent the right to use an underlying asset for the lease term and the lease liabilities represent an obligation to make lease payments arising from the lease, measured at the present value of the lease payments not yet paid discounted using the discount rate for the lease established at the lease commencement date. The operating lease ROU asset also includes any prepaid lease payments made. Lease expense is recognized over the expected lease term on a straight-line basis.

**PRELUDE THERAPEUTICS INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS — Continued**

***Comprehensive loss***

Comprehensive loss includes net loss and certain changes in stockholders' equity that are excluded from net loss. The Company's comprehensive loss for the years ended December 31, 2025 and 2024 comprised net loss and unrealized gain or loss on marketable securities.

***Revenue Recognition***

The Company recognizes revenue under Accounting Standard Codification 606 – *Revenue from Contracts with Customers* ("ASC 606"). Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. The Company's revenue recognition analysis consists of the following steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations; and (v) recognition of revenue as it satisfies each performance obligation.

The Company evaluates all promised goods and services within a customer contract and determines which goods and services are separate performance obligations. This evaluation includes an assessment of whether the good or service is capable of being distinct and whether the good or service is separable from other promises in the contract.

The transaction price is determined based on the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods or services to a customer. The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligations when (or as) the performance obligations are satisfied. The Company recognizes a liability when the Company has received payment but has not yet satisfied the related performance obligations. See note 8 for a full discussion of the Company's revenue contracts. The following table summarizes the changes in deferred revenue:

(in thousands)	Year Ended December 31,
	2025
Beginning balance	\$ -
Deferral of revenue	35,532
Recognition of unearned revenue	-
Ending balance	\$ 35,532

***Stock-Based Compensation***

The Company measures share-based awards at their grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the awards.

Estimating the fair value of share-based awards requires the input of subjective assumptions, including, for stock options, the expected life of the options and stock price volatility. The Company accounts for forfeitures for stock option awards as they occur. The Company uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in estimating the fair value of share-based awards represent management's estimate and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different assumptions, share-based compensation expense could be materially different for future awards.

The expected life of the stock options is estimated using the "simplified method", as the Company has limited historical information from which to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. The simplified method is the midpoint between the vesting period and the contractual term of the option. For stock price volatility, the Company uses its own historical volatility along with comparable public companies as a basis for its expected volatility to calculate the fair value of option grants. The risk-free rate is based on the U.S. Treasury yield curve commensurate with the expected life of the option.

**PRELUDE THERAPEUTICS INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS — Continued**

***Grant Income and Research and Development Tax Credits***

The Company recognizes grants related to income and Delaware research and development tax credits in other income, net in the statements of operations when the necessary qualifying conditions, as stated in the agreements, are met and all contingencies have been resolved. For the years ended December 31, 2025 and 2024, the Company recorded other income related to these items of \$1.2 million and \$2.5 million, respectively. The Company recognizes grants related to assets as deferred income which is included in the balance sheet as other liabilities. The deferred income is then recognized as grant income over the useful life of the related assets.

***Research and Development***

Research and development costs are expensed as incurred. Research and development expenses consist principally of personnel costs, including salaries, stock-based compensation, and benefits of employees, and other operational costs related to the Company's research and development activities, including allocated facility-related expenses and external costs of outside vendors, such as clinical research organizations ("CROs") and clinical manufacturing organizations, and other direct and indirect costs.

The Company accrues an expense or records a prepaid for preclinical studies and clinical trial activities performed by CROs and vendors based upon estimates of the proportion of work completed. These estimates are determined by reviewing contracts, vendor agreements and purchase orders, and through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

Management makes estimates of the Company's accrued research and development expenses as of each balance sheet date in the Company's financial statements based on facts and circumstances known to the Company at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

***Income Taxes***

Income taxes are accounted for under the asset-and-liability method as required by ASC Topic 740, *Income Taxes* ("ASC 740"). Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period corresponding to the enactment date. Under ASC 740, a valuation allowance is required when it is more likely than not all or some portion of the deferred tax assets will not be realized through generating sufficient future taxable income.

ASC Subtopic 740-10, *Accounting for Uncertainty of Income Taxes*, ("ASC 740-10") defines the criterion an individual tax position must meet for any part of the benefit of the tax position to be recognized in financial statements prepared in conformity with GAAP. The Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not such tax position will be sustained on examination by the taxing authorities, based solely on the technical merits of the respective tax position. The tax benefits recognized in the financial statements from such a tax position should be measured based on the largest benefit having a greater than 50% likelihood of being realized upon ultimate settlement with the tax authority. In accordance with the disclosure requirements of ASC 740-10, the Company's policy on income statement classification of interest and penalties related to income tax obligations is to include such items as a component of income tax expense.

**PRELUDE THERAPEUTICS INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS — Continued**

***Net Loss Per Share***

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period, including pre-funded warrants to purchase shares of common stock. Diluted net loss per share of common stock includes the effect, if any, from the potential exercise of securities, such as stock options, and the effect from unvested restricted stock units which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive:

	December 31,	
	2025	2024
Unvested restricted stock units	220,500	56,250
Stock options	14,727,692	14,212,538
	14,948,192	14,268,788

Amounts in the above table reflect the common stock equivalents.

***Recently Issued Accounting Pronouncements***

*Emerging Growth Company Status*

The Company is no longer an emerging growth company as of December 31, 2025 and, as a result, is no longer able to take advantage of reduced disclosure and other obligations that are available to emerging growth companies. However, we still qualify as a “smaller reporting company” which allows us to take advantage of many of the same exemptions from disclosure requirements and other obligations.

*Recently adopted accounting guidance*

In December 2023, the FASB issued ASU Update No. 2023-09, *Income Taxes - Improvements to Income Tax Disclosures*. ASU 2023-09 requires enhanced income tax disclosures related to the rate reconciliation and income taxes paid information. The Company adopted ASU 2023-09 on January 1, 2025 and incorporated the improved income tax disclosures in Note 12, Income Taxes.

*Accounting guidance not yet adopted*

In November 2024, the FASB issued ASU Update No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures*. ASU 2024-03 requires disclosure, in the notes to the financial statements, of specified information about certain costs and expenses. The amendments in this Update are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of this standard but does not expect that it will have a material impact on the financial statements and related disclosures.

**PRELUDE THERAPEUTICS INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS — Continued**

**4. Marketable Securities**

The following is a summary of the Company's marketable securities as of December 31, 2025 and 2024.

(in thousands)	Amortized Cost	Gross unrealized gain	Gross unrealized loss	Fair Value
<b>December 31, 2025:</b>				
Marketable securities				
Corporate debt securities	\$ 31,044	\$ —	\$ (17)	\$ 31,027
U.S. government securities	36,908	23	—	36,931
<b>Total</b>	<b>\$ 67,952</b>	<b>\$ 23</b>	<b>\$ (17)</b>	<b>\$ 67,958</b>
<b>December 31, 2024:</b>				
Marketable securities				
Corporate debt securities	\$ 70,059	\$ 44	\$ (27)	\$ 70,076
U.S. government securities	51,046	18	—	51,064
<b>Total</b>	<b>\$ 121,105</b>	<b>\$ 62</b>	<b>\$ (27)</b>	<b>\$ 121,140</b>

The Company's marketable securities generally have contractual maturity dates of 13 months or less. As of December 31, 2025, the Company had 14 securities with a total fair market value of \$33.1 million in an unrealized loss position. The Company believes that any unrealized losses associated with the decline in value of its securities is temporary and is primarily related to the change in market interest rates since purchase and believes that it is more likely than not that it will be able to hold its marketable securities to maturity.

**5. Fair Value of Financial Instruments**

Fair value is the price that could be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value determination in accordance with applicable accounting guidance requires that a number of significant judgments be made. Additionally, fair value is used on a nonrecurring basis to evaluate assets for impairment or as required for disclosure purposes by applicable accounting guidance on disclosures about fair value of financial instruments. Depending on the nature of the assets and liabilities, various valuation techniques and assumptions are used when estimating fair value. The Company follows the provisions of ASC Topic 820, Fair Value Measurement, for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

- *Level 1:* Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- *Level 2:* Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liabilities.
- *Level 3:* Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

**PRELUDE THERAPEUTICS INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS — Continued**

The following fair value hierarchy table presents information about the Company's assets and liabilities measured at fair value on a recurring basis:

(in thousands)	Fair value measurement at reporting date using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>December 31, 2025:</b>			
Assets:			
Cash equivalents			
Money market funds	\$ 21,620	\$ —	\$ —
U.S. government securities	—	12,461	—
Marketable securities			
Corporate debt securities	—	31,027	—
U.S. government securities	—	36,931	—
<b>Total</b>	<b>\$ 21,620</b>	<b>\$ 80,419</b>	<b>\$ —</b>
<b>December 31, 2024:</b>			
Assets:			
Cash equivalents (Money Market Funds)	\$ 11,246	\$ —	\$ —
Marketable securities			
Corporate debt securities	—	70,076	—
U.S. government securities	—	51,064	—
<b>Total</b>	<b>\$ 11,246</b>	<b>\$ 121,140</b>	<b>\$ —</b>

**6. Property and Equipment**

Property and equipment consisted of the following:

(in thousands)	December 31,	
	2025	2024
Lab equipment	\$ 7,931	\$ 7,920
Leasehold improvements	1,706	1,700
IT equipment	505	505
Furniture and fixtures	1,900	1,900
	12,042	12,025
Less accumulated depreciation	(6,929)	(5,258)
<b>Property and equipment, net</b>	<b>\$ 5,113</b>	<b>\$ 6,767</b>

**7. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	December 31,	
	2025	2024
Compensation and related benefits	\$ 7,138	\$ 9,022
Research and development	4,430	5,416
Other	965	771
	\$ 12,533	\$ 15,209

**PRELUDE THERAPEUTICS INCORPORATED**

**NOTES TO FINANCIAL STATEMENTS — Continued**

**8. Commitments**

*Leases*

The Company leases office and laboratory space in Wilmington, Delaware under a noncancelable lease (the “Chestnut Run Lease”). The premises includes approximately 81,000 rentable square feet and has an initial term of 162 months with 3 five-year extension options and certain expansion rights. Neither the option to extend nor the expansion rights were recognized as part of the Company's measurement of the ROU asset and operating lease liability as of December 31, 2025. Under the terms of the Chestnut Run Lease, the landlord provided an allowance towards the cost of completing tenant improvements for the premises. The Company concluded that the improvements resulting from both the landlord's build-out and the tenant improvements are the landlord's assets for accounting purposes. Costs incurred by the Company related to tenant improvements in excess of the landlord's allowance were treated as prepaid rent and increased the right-of-use asset on the commencement date.

In April 2024, the Company entered into a 12 month finance lease for equipment. The final payment under the agreement was made in April 2025.

Lease cost for each year ended December 31, 2025 and 2024, was \$4.4 million, including \$0.2 million of short-term lease cost.

In November 2025, the Company entered into a sublease agreement with a counterparty to sublease approximately 20,000 square feet of the Chestnut Run Lease. The sublease began in December 2025 and continues through November 2027. The sublessee has three options to extend the sublease for one year each.

The Company analyzed the sublease under ASC Topic 842, Leases (“ASC 842”), and concluded the sublease is a separate lease, as the Company was not relieved of the primary obligation under the Chestnut Run Lease. The Company will continue to account for the Chestnut Run Lease as a lessee and in the same manner as prior to the execution of Sublease Agreement. The Company accounted for the sublease agreement as the lessor, and concluded the sublease qualified as an operating lease, as it did not meet the criteria of a sales-type or direct financing lease. The Company's sublease income was immaterial during the year ended December 31, 2025.

**PRELUDE THERAPEUTICS INCORPORATED**

**NOTES TO FINANCIAL STATEMENTS — Continued**

Supplemental balance sheet and other information related to our operating and finance leases as of December 31, 2025 and 2024 were as follows:

(in thousands) Leases	Classification	December 31, 2025	December 31, 2024
<b>Assets</b>			
Operating	Operating lease right-of-use assets	\$ 27,165	\$ 28,699
Finance	Property and equipment, net	-	523
Total leased assets		<u>\$ 27,165</u>	<u>\$ 29,222</u>
<b>Liabilities</b>			
Current:			
Operating	Current liabilities, operating lease liability	\$ 2,744	\$ 2,492
Finance	Current liabilities, finance lease liability	-	208
Non-Current:			
Operating	Operating lease liability	15,045	15,325
Total lease liabilities		<u>\$ 17,789</u>	<u>\$ 18,025</u>
<b>Weighted-average discount rate</b>			
Operating lease		15.0%	15.0%
Finance lease		0.0%	10.5%
<b>Weighted-average remaining lease term</b>			
(years)			
Operating lease		11.4	12.4
Finance lease		-	0.3

Supplemental cash flow information related to our leases for the twelve months ended December 31, 2025 and 2024 were as follows:

(in thousands)	Year Ended December 31,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating lease	\$ 2,708	\$ 1,583
Operating cash flows from finance lease	5	30
Financing cash flows from finance lease	208	395
Non-cash transaction		
Right-of-use asset obtained in exchange for lease obligations:		
Finance lease	-	603

As of December 31, 2025 future minimum annual lease payments for operating lease are as follows:

(in thousands)	Operating lease
2026	\$ 2,973
2027	3,048
2028	3,124
2029	3,202
2030	3,282
Thereafter	23,093
Total undiscounted lease payments	<u>38,722</u>
Less imputed interest	(20,933)
Lease liability	<u>\$ 17,789</u>

## PRELUDE THERAPEUTICS INCORPORATED

### NOTES TO FINANCIAL STATEMENTS — Continued

The Company paid a security deposit in the form of a letter of credit of \$4.0 million which is included in the accompanying balance sheet as restricted cash. The letter of credit was reduced during the third quarter of 2025 and as of December 31, 2025 the balance was \$3.2 million. The security deposit may be reduced to \$0.5 million over time in accordance with the terms of the Chestnut Run Lease.

In connection with the Company's expansion of operations in the State of Delaware, the Company was approved for two grants from the State of Delaware in 2021 and 2022 totaling \$3.4 million for the development of lab space. The Company has met the minimum requirements stated in the grant agreement in order to not be required to pay back any portion of the \$3.4 million disbursed unless the Company leaves the State of Delaware within five years of disbursement. The Company deferred the recognition of these grant funds as they relate to capitalized costs and has classified them as long-term liabilities in the accompanying balance sheet. The Company recognizes the grant funds in other income over the length of the lease term. During the years ended December 31, 2025 and 2024, the Company recognized \$0.2 million of other income related to this grant.

#### ***Employment Agreements***

The Company entered into employment agreements with key personnel providing for compensation and severance in certain circumstances, as defined in the respective employment agreements.

#### ***401(k) Defined Contribution Plan***

The Company sponsors a 401(k) defined-contribution plan covering all employees. Participants are permitted to contribute up to 100% of their eligible annual pretax compensation up to an established federal limit on aggregate participant contributions. The Company provides a match with a maximum amount of 3% of the participant's compensation. During the years ended December 31, 2025 and 2024 the Company made matching contributions of \$0.7 million and \$0.8 million, respectively.

#### ***Exclusive Option Agreement***

On November 3, 2025, the Company entered into an Exclusive Option Agreement (the "Option Agreement") with Incyte to acquire the Company's mutative selective JAK2V617F JH2 inhibitor program (the "Program") for patients with myeloproliferative neoplasms.

Under the Option Agreement, Incyte received an exclusive option to acquire the Company's entire right, title, and interest in and to certain assets, properties, and rights related to the Program, including the Company's library of preclinical candidates (collectively, the "Transferred Assets") by way of an Asset Purchase Agreement (the "APA"). The Company is continuing to advance the Program. At any time commencing on the effective date of the Option Agreement until the later of (a) 30 days after the Company's delivery of the investigational new drug ("IND") ready data package or (b) 15 months after the effective date of the Option Agreement (which 15 month period shall automatically toll for the Company to deliver the IND-ready package but such tolling will not exceed 3 months unless otherwise agreed by the parties) (the "Option Period"), Incyte may elect to exercise its exclusive option to acquire the Program and associated assets from the Company pursuant to the APA for \$100 million. The Company received an initial upfront payment of \$35 million in cash from the Option Agreement. Under the APA, the Company would be eligible to receive up to \$775 million in additional clinical and regulatory milestones, and single digit royalties on global net sales. Combined, total potential cash payments from the transaction could reach up to \$910 million.

Concurrently with the Option Agreement, the Company entered into a securities purchase agreement with Incyte (the "Securities Purchase Agreement"), pursuant to which Incyte purchased 6,250,000 shares (the "Shares") of the Company's non-voting common stock at a price of \$4.00 per share for gross proceeds of \$25.0 million. Pursuant to the Company's amended and restated certificate of incorporation and subject to the non-voting common stock beneficial ownership limitation, Incyte may elect to convert the Shares into voting shares and in December 2025, Incyte converted 4,372,124 of the Shares into voting shares, making them a related party under SEC regulations. Because the Option Agreement and Securities Purchase Agreement were entered into at the same time and negotiated as single commercial package, the Company accounted for the agreements as a single contract under ASC 606. Based on this exercise, the consideration in the Option Agreement plus any excess consideration paid over the fair value of the equity issued to Incyte is a component of transaction price. In determining the fair value of the common stock issued to Incyte, the Company considered the closing price of the

## PRELUDE THERAPEUTICS INCORPORATED

### NOTES TO FINANCIAL STATEMENTS — Continued

common stock on the date of the transaction, which was \$3.98 per share, which resulted in a premium paid by Incyte of \$0.02 per share, or \$0.1 million (“Equity Premium”). The remaining \$24.9 million was recorded as an issuance of common stock in stockholders’ equity.

The Company will continue to own and develop all Transferred Assets. If the option is exercised during the Option Period and the parties enter into and close the transaction set forth in the APA, Incyte will own all Transferred Assets subject to the Company’s right, in its sole discretion and cost, to continue to conduct development activities during the Option Period to nominate and select development candidate(s) for the Program. If Incyte elects to not exercise its option to acquire the Program, all Transferred Assets would remain in the sole ownership and control of the Company.

The Company first evaluated whether the arrangement meets the definition of a derivative or contains any embedded derivatives under ASC 815, Derivatives and Hedging. Although the arrangement includes underlying IP-related value, it qualifies for the scope exception as prescribed by ASC 815-10-15-59(b). The Company next evaluated whether the arrangement represents a funded research and development arrangement under ASC 730, Research and Development. The payments received by Prelude are non-refundable, and there is no contractual requirement, guarantee, or other provision that would require the Company to repay any of the funds received from Incyte. The Company also concluded that any presumption that there is an obligation to repay the funds received due to the subsequent related party relationship with Incyte is overcome, and therefore the agreements are not within the scope of ASC 730-20. The Company also concluded that the agreements are not within the scope of ASC 808, Collaborative Arrangements. The Company assessed the Option Agreement in accordance with ASC 606, Revenue from Contracts with Customer, and concluded that Incyte is a customer in the context of the Option Agreement. The Option Agreement includes the transfer of the following goods or services: (i) to conduct research and development activities related to the Program and (ii) Incyte's exclusive option to acquire the Company’s entire right, title, and interest in and to certain assets, properties, and rights related to the Program. The Company determined that the exclusive option granted was not a material right and, thus, not a performance obligation.

The Company determined that the transaction price totaled \$35.1 million, which includes the \$35 million upfront cash payment received and the Equity Premium. The Company allocated \$35.1 million to its performance obligations to conduct research and development activities related to the Program. The Company will recognize revenue related to the Option Agreement over time as the performance obligations are satisfied using an inputs approach, by applying actual expenses against total budgeted costs. As of December 31, 2025, \$32.4 million of the upfront payment was included in deferred revenue within the balance sheets which the Company estimates will be recognized within thirteen months from year-end. The Company recognized \$2.6 million in revenue related to the Option Agreement during the year ended December 31, 2025.

#### ***Research Collaboration Agreement***

In 2023, the Company entered into a multi-year, multi-program agreement with AbCellera Biologics Incorporated (“AbCellera”) to jointly discover, develop, and commercialize novel degrader antibody conjugates (“DACs”) for up to five programs (the “Collaboration Agreement”). Under the terms of the agreement, AbCellera will lead manufacturing activities and the Company will lead clinical development and global commercialization, subject to AbCellera’s option to co-promote any resulting commercial products in the United States. The Company concluded that the Collaboration Agreement with AbCellera will be accounted for under the scope of ASC 808, Collaborative Arrangements, as both parties will actively participate in joint operating activities and are exposed to significant risks and rewards. Costs related to the AbCellera collaboration were not material for the years ended December 31, 2025 and 2024.

In August 2025 the Company amended its collaboration with AbCellera (the “Amended Agreement”), and in October 2025, the Company further expanded the collaboration (“the Expanded License Agreement”). The Amended Agreement and Expanded License Agreement provided AbCellera a non-exclusive license to use certain of the Company’s degrader payloads to independently discover, develop and commercialize a select number of DACs against undisclosed antibody targets. The agreements also entailed other changes to overall resource allocation and collaboration governance. For the newly licensed DAC programs, AbCellera received world-wide rights to lead and fully control the licensed programs at its sole cost and expense and the Company is not responsible for any additional financial responsibilities or go forward development costs associated with those programs. The Company received an upfront non-refundable payment from AbCellera of \$6.5 million upon signing the Amended Agreement and an upfront non-refundable payment of \$6.0 million upon signing of the Expanded License Agreement. For the additional licensed DACs, the Company is also eligible to receive customary downstream milestones and single digit royalties on future product sales. The original Collaboration Agreement, whereunder the

**PRELUDE THERAPEUTICS INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS — Continued**

companies can jointly discover, develop, and commercialize novel DACs for up to five programs remains in effect.

The Company assessed the Amended Agreement signed in accordance with ASC 606, Revenue from Contracts with Customer, and concluded that AbCellera is a customer in the context of the Amended Agreement. The Amended Agreement required the Company to transfer certain intellectual property and related know-how to AbCellera which represented the only performance obligation in the Amended Agreement and was satisfied at a point in time, when the intellectual property and related know-how were transferred to AbCellera during the third quarter of 2025. Accordingly, the Company recognized revenue of \$6.5 million during the year ended December 31, 2025 related to the Amended Agreement.

The Company assessed the Expanded Agreement signed in accordance with ASC 606 and concluded that AbCellera is a customer in the context of the Expanded Agreement. The Company determined the promised goods and services included discovering degrader payloads and granting the licenses to the payloads to AbCellera for them to use to research, develop, and commercialize products related to each of the initial targets mutually agreed upon. Each of these licenses is distinct, as AbCellera can derive benefit from each license independent of any other payload. Accordingly, the license to each of the payloads selected by AbCellera represents a separate performance obligation. The delivery of the licenses were the only performance obligations identified in the Expanded Agreement. The transaction price was determined to consist of the upfront payment of \$6.0 million. The Company allocated the transaction price equally across the licenses, as the estimated standalone selling price of each license was equal. Each performance obligation will be fully satisfied at the point in time when the license is transferred to AbCellera. For the year ended December 31, 2025, the Company recognized revenue of \$3.0 million in the statement of operations related to the licenses that were transferred to AbCellera during the year. As of December 31, 2025, the remaining \$3.0 million of the upfront payment was included in deferred revenue within the balance sheets. The Company estimates the remaining performance obligations will be completed in the second half of 2026.

***License Agreement***

In May 2024, the Company and Pathos AI, Inc. ("Pathos") entered into a license agreement under which the Company granted to Pathos an exclusive, sublicensable, world-wide license to its selective, brain-penetrant PRMT5 inhibitor, PRT811. Under the terms of the license agreement, the Company received a \$3.0 million upfront, non-refundable payment. The agreement also included a near term \$4.0 million payment due to the Company upon the earlier of 180 days following the effective date of the license agreement or the execution of a quality agreement between the parties pursuant to which the Company will transfer title to certain quantities of Active Pharmaceutical Ingredient ("API"). In addition, the Company may receive potential developmental milestone payments up to \$37.0 million, potential sales milestone payments up to \$100 million and a range of high single-digit to low double-digit royalties on PRT811 global net sales.

The Company assessed the license agreement with Pathos in accordance with ASC 606 and concluded that Pathos is a customer. The license agreement with Pathos includes the transfer of the following goods or services: (i) exclusive license to PRT811, (ii) transfer of licensed know-how and materials (i.e. datasets, regulatory and manufacturing documents, etc.), (iii) participation in a Joint Communication Committee ("JCC"), and (iv) execution of a quality agreement pursuant to which the Company will transfer title to certain API. The Company evaluated all of the promised goods or services within the contract and determined which goods and services were separate performance obligations. The Company determined that Pathos could not benefit from the license separately from the related know-how and materials, and accordingly, they represent one combined performance obligation. The execution of a quality agreement pursuant to which the Company will transfer title to certain API was identified as a separate performance obligation. The Company also determined the participation in the JCC is immaterial in the context of the license agreement as the Company has no decision-making ability through its participation in the JCC.

The transaction price was allocated to the performance obligations based upon their relative standalone selling prices, which were estimated for (i) the exclusive license and know-how and materials at \$3.0 million using an adjusted market approach and (ii) execution of a quality agreement pursuant to which the Company transferred title to certain API at \$4.0 million using a cost plus margin approach.

With respect to the accounting principles identified above, each performance obligation was recognized at a point in time. The Company determined that the performance obligation for the license and transfer of related know-how and materials was fully satisfied when the license was granted and key know-how and materials were transferred to Pathos as that was the point at which Pathos can fully use and benefit from the license to PRT811. The performance obligation for the execution of a quality agreement pursuant to which the Company transferred title to certain API was satisfied when the legal

**PRELUDE THERAPEUTICS INCORPORATED**

**NOTES TO FINANCIAL STATEMENTS — Continued**

title to the API was transferred. During 2024, the Company satisfied both performance obligations, resulting in \$7.0 million of revenue recognized in the statement of operations for the year ended December 31, 2024.

***Other Research and Development Arrangements***

The Company enters into agreements with CROs to assist in the performance of research and development activities. Expenditures to CROs will represent a significant cost in clinical development for the Company.

**9. Segments**

The Company currently operates as one operating business segment focused on developing innovative medicines in areas of high unmet need for cancer patients. The Company's determination that it operates as a single segment is consistent with the financial information regularly reviewed by the chief operating decision maker ("CODM") for purposes of evaluating performance, allocating resources, and planning and forecasting for future periods.

The accounting policies of the segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for the segment based on net loss, which is reported on the statement of operations and comprehensive loss as net loss. The measure of segment assets is reported on the balance sheet as total assets.

To date, the Company has not recognized any revenue from product sales, and the Company does not expect to generate any revenue from product sales in the foreseeable future. Net loss is used to monitor budget versus actual results. Monitoring budgeted versus actual results is used in assessing performance of the segment and to make decisions about the allocation of resources, along with cash forecast models.

The following tables summarizes the significant expense categories regularly reviewed by the CODM for the years ended December 31, 2025, and 2024. Included in Other are programs such as PRT2527, PRT1419, and PRT3645.

<b>(in thousands)</b>	<b>Year ended December 31,</b>	
	<b>2025</b>	<b>2024</b>
Revenue from license agreement	\$ 12,140	\$ 7,000
Operating expenses:		
Research and development		
PRT3789	\$ 13,461	\$ 20,173
PRT7732	9,145	9,195
Discovery programs, including JAK2V617F, KAT6A and mCALR	12,129	13,856
Other	3,475	12,940
General costs, including personnel related	56,090	61,831
Total research and development	94,300	117,995
General and administrative	22,406	28,719
Total operating expenses	\$ 116,706	\$ 146,714
Loss from operations	(104,566)	(139,714)
Other income, net	5,068	12,541
Net loss	\$ (99,498)	\$ (127,173)

**10. Common Stock**

The Company has two classes of common stock: "voting common stock" and "non-voting common stock." The holders of the voting common stock are entitled to one vote for each share of voting common stock held at all meetings of stockholders. Except as otherwise required by law, the holders of non-voting common stock shall not be entitled to vote at any meetings of stockholders (or written actions in lieu of meetings) and the shares of non-voting common stock shall not be included in determining the number of shares voting or entitled to vote on any matter. Unless required by law, there shall be

**PRELUDE THERAPEUTICS INCORPORATED**

**NOTES TO FINANCIAL STATEMENTS — Continued**

no cumulative voting. Any holder of non-voting common stock may elect to convert each share of non-voting common stock into one fully paid and non-assessable share of voting common stock at any time by providing written notice to the Company; provided that as a result of such conversion, such holder, together with its affiliates and any members of a Schedule 13(d) group with such holder, would not beneficially own in excess of 9.99% of the Company's common stock immediately prior to and following such conversion, unless otherwise as expressly provided for in the Company's restated certificate of incorporation. However, this ownership limitation may be increased (not to exceed 19.99%) or decreased to any other percentage designated by such holder of non-voting common stock upon 61 days' notice to the Company.

***Pre-funded warrants***

There were 1,300,000 pre-funded warrants exercised during the year ended December 31, 2025. There were no pre-funded warrants exercised during the year ended December 31, 2024. As of December 31, 2025, there were 19,532,188 pre-funded warrants outstanding.

***Shelf Registration Statements***

In May 2024, the Company filed a shelf registration statement (the "2024 Shelf Registration Statement") with the SEC for the issuance of common stock, preferred stock, debt securities, warrants, subscription rights and units up to an aggregate amount of \$400 million. The 2024 Shelf Registration statement was declared effective on June 10, 2024. As of December 31, 2025, there was \$400.0 million remaining under the 2024 Shelf Registration Statement.

***Open Market Sales Agreement***

In March 2023, in connection with filing a prospectus supplement to its 2021 Shelf Registration Statement, the Company entered into an Open Market Sales Agreement (the "Sales Agreement") with Jefferies LLC, as the sales agent, pursuant to which the Company may offer and sell shares of its common stock having an aggregate offering amount of up to \$75.0 million. In November 2024, the 2021 Shelf Registration Statement expired with respect to the shares to be sold under the Sales Agreement. Accordingly, the Company will need to register the \$75.0 million of common stock that may be issued and sold pursuant to the Sales Agreement on a subsequent registration statement before any future sales are permitted. The Company will pay Jefferies LLC a commission rate of up to 3.0% of the aggregate gross proceeds from the sale of any shares of common stock pursuant to the Sales Agreement. At December 31, 2025, there was \$75.0 million remaining under the Sales Agreement.

**11. Stock-Based Compensation**

The Company has two equity incentive plans: the 2016 Equity Incentive Plan, as amended, and the 2020 Equity Incentive Plan. New awards can only be granted under the 2020 Equity Incentive Plan (the "Plan") and as of December 31, 2025, 7,449,465 shares were available for future grants. The number of shares of the Company's common stock that may be issued pursuant to rights granted under the Plan shall automatically increase on January 1st of each year and continuing for ten years beginning on January 1, 2021, in an amount equal to five percent of the total number of shares of the Company's common stock outstanding on December 31st of the preceding calendar year, subject to the discretion of the Company's board of directors or compensation committee to determine a lesser number of shares shall be added for such year. On January 1, 2026, 3,147,681 shares were added to the Plan. The Plan provides for the granting of common stock, incentive stock options, nonqualified stock options, restricted stock awards, restricted stock units and/or stock appreciation rights to employees, directors, and other persons, as determined by the Company's board of directors. The Company's stock options vest based on the terms in each award agreement, generally over four-year periods with 25% of options vesting after one year and then monthly thereafter, and have a term of ten years.

The Company measures stock-based awards at their grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the awards. The Company recorded stock-based compensation expense in the following expense categories in its accompanying statements of operations:

(in thousands)	Year Ended December 31,	
	2025	2024
Research and development	\$ 6,938	\$ 12,134
General and administrative	4,975	9,211
	<u>\$ 11,913</u>	<u>\$ 21,345</u>

**PRELUDE THERAPEUTICS INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS — Continued**

**Stock Options**

The following table summarizes stock option activity for the Plan in the years indicated:

	Number of shares	Weighted average exercise price per share	Weighted average remaining contractual term (years)
Outstanding at January 1, 2024	11,898,446	\$ 10.60	7.77
Granted	3,922,800	\$ 4.40	
Exercised	(14,955)	\$ 3.98	
Forfeited	(1,593,753)	\$ 9.09	
Outstanding at December 31, 2024	<u>14,212,538</u>	\$ 9.07	7.30
Granted	3,791,285	\$ 1.12	
Exercised	(12,315)	\$ 1.26	
Forfeited	(3,263,816)	\$ 6.11	
Outstanding at December 31, 2025	<u>14,727,692</u>	\$ 7.68	6.80
Exercisable at December 31, 2025	<u>9,532,796</u>	\$ 10.37	5.85

The aggregate intrinsic value of options exercised was immaterial during the years ended December 31, 2025 and 2024. At December 31, 2025, the aggregate intrinsic value of outstanding options and exercisable options was \$7.5 million and \$2.0 million, respectively.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2025 under the Plan:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.31 - \$1.66	3,360,636	8.62	\$ 1.12	276,555	\$ 1.22
\$1.67 - \$4.67	4,425,284	6.68	3.50	2,961,943	3.06
\$4.68 - \$11.72	3,876,187	6.75	7.31	3,228,713	7.40
\$11.73 - \$88.98	3,065,585	5.04	21.38	3,065,585	21.38
	<u>14,727,692</u>			<u>9,532,796</u>	

The weighted-average grant date fair value of options granted was \$0.83 and \$3.25 per share for the years ended December 31, 2025 and 2024, respectively. The Company recorded stock-based compensation expense of \$11.6 million and \$20.8 million for the years ended December 31, 2025 and 2024, respectively, related to stock options. As of December 31, 2025, the total unrecognized compensation expense related to unvested stock option awards was \$9.5 million, which the Company expects to recognize over a weighted-average period of 1.8 years.

The fair value of each option was estimated on the date of grant using the weighted average assumptions in the table below:

	Year Ended December 31,	
	2025	2024
Expected volatility	86.54%	84.96%
Risk-free interest rate	4.27%	4.19%
Expected life (in years)	6.00	6.05
Expected dividend yield	—	—

**PRELUDE THERAPEUTICS INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS — Continued**

***Restricted Stock Units***

The Company issues restricted stock units (“RSU”) to employees that generally vest over a four-year period with 25% of awards vesting after one year and then quarterly thereafter. Any unvested shares will be forfeited upon termination of services.

The following table summarizes activity related to RSU stock-based payment awards:

	Number of shares	Weighted- average grant date fair value
Outstanding at January 1, 2024	103,750	\$ 6.16
Vested	(42,500)	\$ 6.44
Forfeited	(5,000)	\$ 18.32
Outstanding at December 31, 2024	<u>56,250</u>	\$ 4.86
Granted	349,500	\$ 1.11
Vested	(37,500)	\$ 4.86
Forfeited	(147,750)	\$ 1.11
Outstanding at December 31, 2025	<u><u>220,500</u></u>	\$ 1.43

The Company recorded stock-based compensation expense of \$0.2 million and \$0.3 million for the years ended December 31, 2025 and 2024, respectively, related to RSUs. At December 31, 2025 the total unrecognized expense related to the RSUs was \$0.2 million, which the Company expects to recognize over a weighted-average period of 2.5 years.

***Employee Stock Purchase Plan***

The Company has an Employee Stock Purchase Plan (the “ESPP”), which as of December 31, 2025 had 2,308,269 shares of common stock reserved for future issuance. The number of shares of the Company’s common stock that may be issued pursuant to rights granted under the ESPP shall automatically increase on January 1st of each year and continuing for ten years beginning in 2021, in an amount equal to one percent of the total number of shares of all classes of the Company’s common stock outstanding on December 31st of the preceding calendar year, subject to the discretion of the Company’s board of directors or compensation committee to determine a lesser number of shares shall be added for such year. On January 1, 2026, 629,536 shares were added to the ESPP.

Under the ESPP, eligible employees can purchase the Company’s common stock through accumulated payroll deductions at such times as are established by the Company’s compensation committee. Eligible employees may purchase the Company’s common stock at 85% of the lower of the fair market value of the Company’s common stock on the first day of the offering period or on the last day of the offering period. Eligible employees may contribute up to 15% of their eligible compensation. Under the ESPP, a participant may not accrue rights to purchase more than \$25,000 worth of the Company’s common stock for each calendar year in which such right is outstanding.

The ESPP is considered compensatory under the FASB stock compensation rules. Accordingly, share-based compensation expense is determined based on the option’s grant-date fair value as estimated by applying the Black Scholes option-pricing model and is recognized over the withholding period. The Company recognized share-based compensation expense of \$0.1 million and \$0.2 million for the years ended December 31, 2025 and 2024, respectively, related to the ESPP.

**12. Income Taxes**

For the years ended December 31, 2025 and 2024, the Company recorded a provision for income taxes of \$0.

The Company’s loss before income taxes in the United States (“U.S.”) for the years ended December 31, 2025 and 2024 was \$99.5 million and \$127.2 million, respectively. The Company has no foreign operations.

**PRELUDE THERAPEUTICS INCORPORATED**

**NOTES TO FINANCIAL STATEMENTS — Continued**

The Company adopted ASU 2023-09 prospectively in the 2025 reporting period. The prior year rate reconciliation presentation has not been recast and is, therefore, not comparable to the current year presentation. A reconciliation of the U.S. federal statutory income tax rate to the Company's effective tax rate pursuant to the disclosure requirements of ASU 2023-09 is as follows (in millions, except for percentages):

	Year ended December 31,			
	2025		2024	
U.S. federal statutory income tax rate	\$ (20,894)	21.0 %	21.0	%
State and local income taxes, net of federal income tax effect <sup>(1)</sup>	-	-	6.6	
<b>Tax credits</b>				
Federal research and development	(4,531)	4.6	2.4	
Changes in valuation allowance	23,218	(23.4)	(27.5)	
<b>Nontaxable or nondeductible items</b>				
Other permanent differences	833	(0.8)	(1.0)	
<b>Other adjustments</b>				
Share-based compensation	1,374	(1.4)	(1.5)	
Effective tax rate	<u>\$ -</u>	<u>- %</u>	<u>-</u>	<u>%</u>

(1) Greater than 50% of the state and local taxes, net of federal income tax effect, is attributable to the State of Delaware.

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets and liabilities were as follows:

(in thousands)	December 31,	
	2025	2024
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 112,873	\$ 81,520
Research and development credits	28,199	23,668
Research and development capitalization	41,784	59,341
Stock-based compensation	15,709	15,312
Accrued expenses and other	13,064	2,783
Lease liabilities	4,961	5,033
Gross deferred tax assets	216,590	187,657
Less: valuation allowance	(211,904)	(182,642)
Total deferred tax asset	4,686	5,015
<b>Deferred tax liability</b>		
Right-of-use assets	(4,304)	(4,595)
Depreciation	(382)	(420)
Total deferred tax liabilities	(4,686)	(5,015)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

The deferred tax assets, net of valuation allowance of \$4.7 million and \$5.0 million as of December 31, 2025 and 2024, respectively, primarily consists of net operating loss, tax credit carryforwards and capitalized research and development expenses for income tax purposes. As required by the 2017 Tax Cuts and Jobs Act, effective January 1, 2022, the Company's research and development expenditures were capitalized, resulting in a deferred tax asset. As amended by the One Big Beautiful Bill Act (OBBBA), effective July 2025, the Company's current year US research and development expenditures were deducted resulting in a reduction of the capitalized R&D deferred tax asset. Due to the Company's history of operating losses, the Company recorded a valuation allowance on its net deferred tax assets by increasing the valuation allowance by \$29.3 million and \$35.0 million during the years ended December 31, 2025 and 2024, respectively, as it was more likely than not that such tax benefits will not be realized.

**PRELUDE THERAPEUTICS INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS — Continued**

The following table summarizes carryforwards of federal and state net operating losses (“NOL”) and research tax credits:

(in thousands)	December 31,	
	2025	2024
NOL carryforwards - Federal	\$ 432,626	\$ 292,193
NOL carryforwards - State	320,831	293,621
Research tax credits - Federal	28,166	23,634
Research tax credits - State	43	43

At December 31, 2025, the Company had federal net operating loss (NOL) carryforwards for income tax purposes of approximately \$432.6 million and federal tax credit carryforwards of \$28.2 million. The NOL carryforwards begin expiring in 2036 for federal and Delaware state income tax purposes; however, all federal, Delaware state, and Kansas state NOL carryforwards generated subsequent to January 1, 2018, can be carried forward indefinitely. The NOL carryforwards begin expiring in 2037 and 2042 for Tennessee and Massachusetts, respectively. As of December 31, 2025, the Company also had federal and Delaware research and development tax credit carryforwards of \$28.2 million and \$43 thousand, respectively, that will begin to expire in 2039 and 2031, respectively, unless previously utilized.

The NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. To date, the Company has not performed an analysis to determine whether ownership changes have occurred since inception. Delaware state NOLs may also be limited.

As of December 31, 2025, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company’s statement of operations. Due to NOL and tax credit carry-forwards that remain unutilized, income tax returns for all tax years remain subject to examination by the taxing jurisdictions. The NOL carryforwards remain subject to review until utilized.

During the years ended December 31, 2025 and 2024, the Company did not have any significant income taxes paid.

**13. Workforce Reduction**

During 2025, the Company reduced its workforce by approximately 27% of full-time employees to align its resources with its ongoing clinical and preclinical programs. The one-time severance costs related to the workforce reductions were \$1.3 million, of which \$1.2 million and \$0.1 million are included within research and development and general and administrative expense, respectively, in the accompanying statement of operations.

The following table summarizes the activity recorded in connection with the reduction in workforce for the year ended December 31, 2025 within accrued expenses and other current liabilities on the balance sheet:

(in thousands)	Amount accrued at December 31, 2024	Charges	Amount Paid	Adjustments	Amount accrued at December 31, 2025
Workforce reduction	\$ -	1,322	(611)	-	\$ 711

**PRELUDE THERAPEUTICS INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS — Continued**

**Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.**

None.

**Item 9A. Controls and Procedures.****Evaluation of Disclosure Controls and Procedure**

Under the supervision and with the participation of our management, including our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal accounting officer), we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2025. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on our management’s evaluation (with the participation of our Chief Executive Officer and our Chief Financial Officer), as of the end of the period covered by this report, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

**Management’s Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate. Our internal control over financial reporting is a process designed under the supervision of our principal executive officer and principal financial officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

Our management conducted an assessment of our internal control over financial reporting based on the framework established in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013). Based on the assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**Item 9B. Other Information.**

None.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.**

Not applicable.

## PART III

### **Item 10. Directors, Executive Officers and Corporate Governance.**

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

The Company has adopted a policy statement regarding securities transactions (the "Trading Policy") that applies to all officers, directors, employees, consultants, and contractors of the Company and its subsidiaries, as well as the Company itself. The Company believes that the Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations with respect to the purchase, sale and/or other dispositions of the Company's securities. A copy of the Trading Policy is filed as Exhibit 19 to this Annual Report on Form 10-K.

### **Item 11. Executive Compensation**

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

### **Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

### **Item 14. Principal Accounting Fees and Services.**

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

## PART IV

### Item 15. Exhibit and Financial Statement Schedules.

(1) *Financial Statements:*

The financial statements required by Item 15(a) are filed as part of this Annual Report on Form 10-K under Item 8 “Financial Statements and Supplementary Data.”

(2) *Financial Statement Schedules*

The financial statement schedules required by Item 15(a) are omitted because they are not applicable, not required or the required information is included in the financial statements or notes thereto as filed in Item 8 of this Annual Report on Form 10-K.

(3) *Exhibits.*

Exhibit Number	Exhibit Title	Incorporated by Reference			Filed Herewith
		Form	File No.	Exhibit	
3.1	<a href="#">Amended and Restated Certificate of Incorporation of Prelude Therapeutics Incorporated.</a>	10-Q	001-39527	3.1	August 14, 2025
3.2	<a href="#">Amended and Restated Bylaws of Prelude Therapeutics Incorporated.</a>	8-K	001-39527	3.1	January 23, 2023
4.1	<a href="#">Form of Common Stock Certificate.</a>	S-1/A	333-248628	4.1	September 16, 2020
4.2	<a href="#">Amended and Restated Investors' Rights Agreement, dated August 21, 2020, by and among Prelude Therapeutics Incorporated and certain of its stockholders</a>	S-1	333-248628	4.2	September 4, 2020
4.3	<a href="#">Form of Registration Rights Agreement, by and among Prelude Therapeutics Incorporated and certain of its stockholders.</a>	S-1	333-251874	4.3	January 4, 2021
4.4	<a href="#">Form of Amended and Restated Registration Rights Agreement by and among Prelude Therapeutics Incorporated and certain Investors.</a>	10-K	001-39527	4.4	February 15, 2024
4.5	<a href="#">Description of Voting Common Stock Registered Under Section 12 of the Securities Exchange Act of 1943, as amended.</a>	10-K	001-39527	4.5	February 15, 2024
4.6	<a href="#">Form of Pre-Funded Warrant</a>	8-K	001-39527	4.1	May 19, 2023
4.7	<a href="#">Form of Pre-Funded Warrant</a>	8-K	001-39527	4.1	December 11, 2023
10.1+	<a href="#">Form of Indemnification Agreement with directors and officers.</a>	S-1	333-248628	10.1	September 4, 2020
10.2+	<a href="#">2016 Stock Incentive Plan, as amended, and forms of award agreements.</a>	S-1	333-248628	10.2	September 4, 2020
10.3+	<a href="#">2020 Equity Incentive Plan and forms of award agreements.</a>	S-1/A	333-248628	10.3	September 21, 2020
10.4+	<a href="#">2020 Employee Stock Purchase Plan and forms of award agreements.</a>	S-1/A	333-248628	10.4	September 21, 2020
10.5+	<a href="#">Executive Employment Agreement, dated December 30, 2020, by and between the Prelude Therapeutics Incorporated and Krishna Vaddi.</a>	S-1	333-251874	10.6	January 4, 2021

Exhibit Number	Exhibit Title	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.6+	<a href="#">Executive Employment Agreement, dated December 19, 2020, by and between Prelude Therapeutics Incorporated and Peggy Scherle</a>	10-K	001-39527	10.7	March 17, 2022	
10.7+	<a href="#">Amended Executive Employment Agreement, dated February 4, 2025, by and between Prelude Therapeutics Incorporated and Bryant Lim</a>	10-K	001-39527	10.7	March 10, 2025	
10.8††	<a href="#">Single-Tenant Triple Net Lease, dated September 13, 2021, by and between Prelude Therapeutics Incorporated and Crisp Partners, LLC.</a>	10-K	001-39527	10.11	March 17, 2022	
10.09††	<a href="#">First Amendment to Single-Tenant Triple Net Lease, dated November 15, 2021, by and between the Prelude Therapeutics Incorporated and Crisp Partners, LLC.</a>	10-K	001-39527	10.12	March 17, 2022	
10.10††	<a href="#">Second Amendment to Single-Tenant Triple Net Lease, dated August 8, 2022, by and between Prelude Therapeutics Incorporated and CRISP Partners LLC.</a>	10-Q	001-39527	10.1	November 14, 2022	
10.11	<a href="#">Open Market Sale Agreement <sup>SM</sup>, dated March 15, 2023, by and between Prelude Therapeutics Incorporated and Jefferies LLC.</a>	8-K	001-39527	1.1	March 15, 2023	
10.12	<a href="#">Form of Securities Purchase Agreement by and among Prelude Therapeutics Incorporated and certain Investors.</a>	10-K	001-39527	10.13	February 15, 2024	
10.13††	<a href="#">Exclusive Option Agreement, dated November 3, 2025, by and between Prelude Therapeutics Incorporated and Incyte Corporation</a>					X
10.14	<a href="#">Registration Rights Agreement, dated November 10, 2025, by and between Prelude Therapeutics Incorporated and Incyte Corporation</a>					X
10.15††	<a href="#">Consulting Agreement dated November 3, 2025 by and between Prelude Therapeutics Incorporated and Jane Huang</a>					X
19	<a href="#">Insider Trading Policy</a>	10-K	001-39527	19	March 10, 2025	
21.1	<a href="#">Subsidiaries of Prelude Therapeutics Incorporated.</a>	10-K	001-39527	21.1	February 15, 2024	
23.1	<a href="#">Consent of Ernst and Young LLP, an independent registered public accounting firm.</a>					X
31.1	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>					X
31.2	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>					X
32.1*	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>					X

Exhibit Number	Exhibit Title	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
32.2*	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>					X
97.1	<a href="#">Compensation Recovery Policy of Prelude Therapeutics Incorporated</a>	10-K	001-39527	97.1	February 15, 2024	
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).					X

+ Indicates a management contract or compensatory plan, contract or arrangement.

^ The registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.

†† Certain of the exhibits and schedules to these exhibits have been omitted in accordance with Regulation S-K Item 601(a)(5). The registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

\* This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

#### Item 16. Form 10-K Summary

None.



CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

[\*\*\*] INDICATES THAT INFORMATION HAS BEEN REDACTED.

**Exhibit 10.13**

**EXCLUSIVE OPTION AGREEMENT**

by and between

**Incyte Corporation**

and

**Prelude Therapeutics Incorporated**

dated as of November 3, 2025

## EXCLUSIVE OPTION AGREEMENT

This EXCLUSIVE OPTION AGREEMENT (the “Agreement”) is entered into as of November 3, 2025 (the “Effective Date”), by and between Incyte Corporation, a Delaware corporation (“Incyte”), and Prelude Therapeutics Incorporated, a Delaware corporation (“Prelude”).

WHEREAS, Prelude is a biopharmaceutical company in the business of discovering and developing a portfolio of precision oncology therapeutics;

WHEREAS, Incyte is a biopharmaceutical company in the business of research, development and commercialization of biopharmaceutical products;

WHEREAS, Prelude is conducting research and development activities relating to V617F Mutative Selective Inhibitors (as defined below);

WHEREAS, Incyte desires to obtain from Prelude, and Prelude desires to grant to Incyte, an exclusive option to acquire the Transferred Assets (as such term is defined in the Asset Purchase Agreement), in each case, in accordance with the terms and conditions set forth in this Agreement; and

WHEREAS, concurrently with the execution of this Agreement, Incyte and Prelude have entered into that certain securities purchase agreement (the “Securities Purchase Agreement”), pursuant to which Incyte has agreed to purchase 6,250,000 shares of non-voting common stock of Prelude for a total of \$25 million, on the terms and subject to the conditions set forth therein.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

### **ARTICLE I** **DEFINITIONS**

When used in this Agreement, each of the following terms shall have the meanings set forth in this ARTICLE I:

1.1 “Affiliate” means, with respect to a Person, any entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. For this purpose, “control” means the ownership of fifty percent (50%) or more of the voting securities entitled to elect the directors or management of the entity, or the actual power to elect or direct the management or policies of the entity, whether by law, contract or otherwise.

1.2 “Asset Purchase Agreement” means the asset purchase agreement substantially in the form attached hereto as Exhibit A to be entered into between the Parties pursuant to Section 5.1(b).

1.3 [\*\*\*].

1.4 “Business” means the research, Development, Manufacture, use, Regulatory Activities, Commercialization or other exploitation of the V617F Molecules anywhere in the world, including the conduct of the V617F Program.

1.5 “Business Day” means any day except Saturday, Sunday and any day on which banking institutions in New York, New York or Wilmington, Delaware generally are closed as a result of federal, state or local holiday.

1.6 “Change of Control” means, with respect to either Party, the occurrence of any of the following after the Effective Date: (a) the acquisition by a Third Party, in one transaction or a series of related transactions, of direct or indirect beneficial ownership of more than fifty percent (50%) of the outstanding voting equity securities of such Party; (b) a merger, reorganization or consolidation involving such Party, as a result of which a Third Party acquires direct or indirect beneficial ownership of more than fifty percent (50%) of the voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a sale of all or substantially all of the assets of such Party in one transaction or a series of related transactions to a Third Party.

1.7 “Closing” means the closing of the purchase and sale of the Transferred Assets (as such term is defined in the Asset Purchase Agreement) and assumption of the Assumed Liabilities (as such term is defined in the Asset Purchase Agreement) under the Asset Purchase Agreement.

1.8 “Commercialize”, “Commercialization” or “Commercializing” means any activities directed toward maintaining Regulatory Approvals, obtaining and maintaining pricing or reimbursement approvals, marketing, promoting, distributing, importing, offering to sell, or selling a product (including establishing the price for such product).

1.9 “Commercially Reasonable Efforts” means, with respect to the efforts to be expended by Prelude in relation to any V617F Molecule, the reasonable, diligent, good-faith efforts that a prudent biopharmaceutical company of comparable size and resources would devote to achieve the specified objective for any other product owned by it or in relation to which it may have rights [\*\*\*].

1.10 “Confidential Information” means, with respect to a Party, any and all confidential or proprietary documents, technology, Know-How or other information (whether or not patentable) actually disclosed by or on behalf of one Party or any of its Affiliates to the other pursuant to this Agreement or the Confidentiality Agreements, which may include specifications, Know-How, trade secrets, technical information, models, business information, inventions, discoveries, methods, procedures, formulae, protocols, techniques, data, and unpublished Patent applications, whether disclosed in oral, written, graphic, or electronic form; provided that Confidential Information does not include any information that (a) is or becomes publicly available through no breach of this Agreement by the receiving Party or its Representatives; (b) was rightfully known to the receiving Party or its Representatives, without confidentiality restrictions, prior to disclosure by the disclosing Party; (c) is independently developed by the receiving Party or its Representatives without use of or reference to any Confidential Information of the disclosing Party; or (d) is rightfully obtained by the receiving Party from a Third Party who, to the receiving Party’s knowledge, is not under a duty of confidentiality with respect to such information.

1.11 “Confidentiality Agreements” means (a) the Mutual Confidential Disclosure Agreement by and between Incyte and Prelude, dated March 3, 2022, as amended on February 9, 2024 and December 17, 2024 and (b) the Clean Team Agreement by and between Incyte and Prelude, dated March 3, 2025, as amended on October 7, 2025 and October 8, 2025.

1.12 “Convicted Individual” or “Convicted Entity” is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

1.13 “Debarred Entity” is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or Affiliate of a Debarred Entity.

1.14 “Debarred Individual” is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a Person that has an approved or pending drug or biological product application.

1.15 “Develop” or “Development” means any and all (a) activities related to the design, discovery, generation, identification, profiling, selection, optimization, characterization, process science, formulation and manufacturing process development, pre-clinical development or non-clinical or pre-clinical studies of drug candidates, products and components thereof, including manufacturing in support thereof, and (b) activities related to test method development and stability testing, toxicology, formulation and manufacturing process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical trials (conducted before and after Regulatory Approval), including manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining, maintaining or expanding a Regulatory Approval. For clarity, “Develop” and “Development” shall include any submissions and activities required by applicable Laws or a Regulatory Authority as a condition or in support of obtaining a pricing or reimbursement approval for an approved product.

1.16 “Diligent Efforts” means, with respect to the efforts to be expended by Prelude in relation to any V617F Molecule [\*\*\* ].

1.17 “Drug Approval Application” means (a) a New Drug Application (as defined in the U.S. Federal Food, Drug and Cosmetics Act and the regulations promulgated thereunder (21 C.F.R. §312)) or (b) a Biologics License Application (as more fully described in 21 C.F.R. § 601.20 or its successor regulation), including all supplements, amendments, variations, extensions and renewals of any such application and any application for approval under the FDA accelerated approval program.

1.18 “Encumbrance” means any lien, pledge, hypothecation, mortgage, security interest, encumbrance, right of first refusal, preemptive right or similar restriction of any nature.

1.19 “Excluded Individual” or “Excluded Entity” is (a) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (b) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

1.20 “Executive Officers” means the Chief Executive Officer of Incyte (or a senior executive officer of Incyte designated by Incyte’s Chief Executive Officer) and the Chief Executive Officer of Prelude (or a senior executive officer of Prelude or its Affiliate as designated by Prelude’s Chief Executive Officer).

1.21 “FDA” means the United States Food and Drug Administration, or any successor agency thereto or authority in the United States having substantially the same function.

1.22 [\*\*\*]

1.23 “GLP” means good laboratory practice as required by the FDA under 21 C.F.R. part 58 and all applicable Laws, and the requirements with respect to current good laboratory practices prescribed by the European Community, the OECD (Organization for Economic Cooperation and Development Council) and the ICH Guidelines, or as otherwise required by applicable Laws.

1.24 “GLP Toxicology Study” means, with respect to a V617F Molecule, the pre-clinical toxicology studies [\*\*\*] conducted under GLP with respect to such V617F Molecule for the purposes of [\*\*\*] in order to establish a toxicological profile of such V617F Molecule [\*\*\*].

1.25 “Governmental Authority” means any multinational, supra-national, federal, state, local, municipal or other governmental authority of any nature (including any Regulatory Authority and any governmental association, division, prefecture, subdivision, department, agency, bureau, branch, office, commission, committee, council, court or other tribunal, such as statutory health insurance funds and their associations), in each case having jurisdiction over the applicable subject matter.

1.26 “HSR Act” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and any regulations promulgated thereunder.

1.27 “IND” means an Investigational New Drug Application (as defined in the U.S. Federal Food, Drug and Cosmetics Act and the regulations promulgated thereunder (21 C.F.R. §312)), or any other investigational new drug application, clinical trial authorization, or similar application, submission, or a clinical trial exemption of any country or jurisdiction outside of the U.S., in each case, which must be approved, cleared or authorized by the applicable Regulatory Authority to commence or conduct any clinical trial of a pharmaceutical or biological product in humans in such jurisdiction, and all supplements and amendments to any of the foregoing.

1.28 “IND Ready Data Package” means a data package with respect to Development activities (including IND-Enabling Studies) conducted by or on behalf of Prelude for [\*\*\*].

1.29 “Initial Data Package” means a data package with respect to Development activities conducted by or on behalf of Prelude [\*\*\*], which contains the following (provided that the applicable data or information is in existence and in the control of Prelude (or any of its Affiliates) as of the time of the Initial Data Package Delivery Date): (a) the data (as outlined in the Target Candidate Profile) [\*\*\*]; (b) any then-available data on [\*\*\*] (including, as applicable [\*\*\*] other than [\*\*\*]; and (c) any Regulatory Materials [\*\*\*].

1.30 “Intellectual Property Rights” means all intellectual property and industrial property rights of every kind and description throughout the world, including all (a) Patents, (b) Know-How, (c) trademarks, service marks, names, corporate names, trade names, logos, slogans, trade dress, design rights, internet domain names, social media designations and other similar designations of source or origin, together with the goodwill symbolized by any of the foregoing and applications and registrations for the foregoing, and (d) copyrights and copyrightable subject matter, including any applications and registrations for the foregoing.

1.31 “Know-How” means any information, ideas, data, inventions, works of authorship, database rights, trade secrets, technology, practices, techniques, procedures, knowledge, skill, experience or materials, including formulations, molecules, assays, reagents, compounds, biologic molecules, compositions, human or animal tissue, samples or specimens, and combinations or components thereof, whether or not proprietary or patentable, or public or confidential, and whether stored or transmitted in oral, documentary, electronic or other form, including all Regulatory Materials, but excluding any such information or materials publicly disclosed in Patents.

1.32 “Law” means any federal, state, regional, county and local law, statute, ordinance, legally binding rule, directive or regulation, code, judgment, constitution, principle of common law, edict, treaty, ruling or directive or similar regulation of general applicability of (a) any government, governmental or quasi-governmental authority, entity, ministry, department, commission, board, agency or instrumentality, (b) any court, tribunal, or judicial or arbitral body, whether federal, state, provincial local or foreign and (c) any body exercising or entitled to exercise any administrative, executive, judicial, legislative, regulatory or tax authority or power of any nature.

1.33 “Liabilities” means any and all debts, liabilities, commitments and obligations of any kind, whether fixed, contingent or absolute, matured or unmatured, liquidated or unliquidated, accrued or not accrued, asserted or not asserted, known or unknown, determined, determinable or otherwise, whenever or however arising (including, whether arising out of any contract or tort based on negligence or strict liability).

1.34 “Losses” means any actual out-of-pocket damages, losses, payments, Liabilities, deficiencies, assessments, interest, penalties, fees, costs (including reasonable and documented out-of-pocket costs of investigation and defense), amounts paid in settlement and expenses (including reasonable and documented attorneys’ fees and expenses).

1.35 “Manufacturing” or “Manufacture” means all activities related to the manufacturing of any molecule or product, or a combination or comparator product, or any ingredient thereof, including manufacturing for non-clinical or clinical use or commercial sale,

in-process and lot release testing, release, certification, filling, labelling and packaging, quality assurance activities related to such aforementioned manufacturing as well as handling and storage of any such molecule, product or ingredient.

1.36 “Option Period” means the period commencing on Effective Date and ending on the later of (a) the end of the Data Package Review Period and (b) the end of the fifteen (15)-month period after the Effective Date, as such period may be extended pursuant to Section 4.1(b) or otherwise by mutual agreement of the Parties.

1.37 “Party” means Prelude or Incyte. “Parties” means Prelude and Incyte.

1.38 “Patents” means all patents and patent applications in any country in the world, including any continuations, continuations-in-part, divisionals, non-provisionals, provisionals, any international application under the Patent Cooperation Treaty, regional application, or any substitute applications, any patent issued with respect to any such patent applications, any reissue, reexamination, renewal or extension (including any patent term extension or supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all counterparts or equivalents of any of the foregoing anywhere in the world.

1.39 “Permitted Encumbrance” means (a) any Encumbrance for Taxes that are not due and payable, and (b) in the case of any contract, Encumbrances that are restrictions against the transfer or assignment thereof that are included in the terms of such contract.

1.40 “Person” means any natural person and any corporation, company, partnership (general or limited), unincorporated association (whether or not having separate legal personality), trust, Governmental Authority or other entity.

1.41 “Regulatory Activities” means activities with respect to (a) preparation, filing, obtaining and maintaining Regulatory Approvals, (b) preparation of Regulatory Materials and (c) calls and meetings with Regulatory Authorities.

1.42 “Regulatory Approval” means all approvals, licenses, registrations, and authorizations of any federal, national, multinational, state, provincial or local Regulatory Authority, department, bureau and other Governmental Authority that are necessary for the marketing and sale of a product in a country or group of countries.

1.43 “Regulatory Authority” means, with respect to a country, the regulatory authority or regulatory authorities of such country (including state and local) with authority over the testing, Manufacture, use, storage, disposal, importation, promotion, marketing, pricing or sale of a pharmaceutical or biologic product in such country.

1.44 “Regulatory Materials” means regulatory applications, submissions, notifications, communications, correspondence, registrations or other filings submitted to, made to, received from or otherwise conducted with a Regulatory Authority that are necessary in order to Develop, Manufacture, obtain and maintain Regulatory Approvals, market, sell or otherwise Commercialize any V617F Molecule in a particular country or regulatory jurisdiction. Regulatory Materials

include materials relating to pre-IND meetings, INDs, pre-Marketing Authorization Applications, Marketing Authorization Applications, presentations, responses, and applications for other Regulatory Approvals.

1.45 “Related to the Business” means exclusively related to, or used exclusively in connection with, the Business as conducted by Prelude and its Affiliates.

1.46 “Representative” of a Person means any Affiliate, officer, director, manager, employee, stockholder, member or equityholder of such Person or any investment banker, attorney, accountant or other advisor, agent or representative of such Person.

1.47 “SEC” means the United States Securities and Exchange Commission.

1.48 [\*\*\*].

1.49 [\*\*\*].

1.50 “Subsidiary” means, with respect to any Person, any other Person of which at least a majority of the securities or ownership interests having by their terms ordinary voting power to elect a majority of the board of directors or other Persons performing similar functions is directly or indirectly owned or controlled by such Person or by one or more of its Subsidiaries.

1.51 “Tax” means any tax (including any net income tax, gross income tax, franchise tax, capital gains tax, gross receipts tax, gross profits tax, branch profits tax, windfall profits tax, capital tax, value-added tax, surtax, estimated tax, employment tax, unemployment tax, national health insurance tax, severance tax, social security tax or other similar contribution, disability tax or other similar contribution, occupancy tax, excise tax, estimated tax, alternative or minimum tax, ad valorem tax, transfer tax, stamp tax, documentary tax, premium tax, sales tax, use tax, service tax, property tax, business tax, capital stock tax, withholding tax, backup tax or payroll tax), levy, assessment, tariff, impost, imposition, duty (including any customs duty), or other tax or charge of any kind whatsoever, imposed, assessed or collected by or under the authority of any Governmental Authority, together with any interest, penalties, inflationary adjustments, additions to tax, fines or other additional amounts imposed thereon, with respect thereto, or related thereto.

1.52 “Third Party” means any Person other than a Party or an Affiliate of a Party.

1.53 “Transaction Proposal” means [\*\*\*].

1.54 “United States” or “U.S.” means the United States of America and its territories and possessions.

1.55 “V617F Assets” means the assets, properties and rights of Prelude and its Affiliates that are Related to the Business.

1.56 “V617F Know-How” means all Know-How owned by Prelude and its Affiliates as of the Effective Date or otherwise during the Option Period that are Related to the Business.

1.57 “V617F Molecules” means (a) all V617F Mutative Selective Inhibitors that are owned and controlled by Prelude or its Subsidiaries as of the Effective Date [\*\*\*].

1.58 “V617F Mutative Selective Inhibitors” means any molecules that bind the JAK2 pseudokinase domain (JH2) [\*\*\*].

1.59 “V617F Patents” means all Patents owned by Prelude and its Affiliates as of the Effective Date or otherwise during the Option Period that are Related to the Business, including the Patents set forth on Schedule 1.59.

1.60 “V617F Program” means the Development program(s) carried out by or on behalf of Prelude and its Affiliates with respect to V617F Mutative Selective Inhibitors.

1.61 “V617F Program Data” means all data with respect to V617F Molecules made, collected or otherwise generated in the conduct of the V617F Program under this Agreement.

1.62 Additional Definitions. Each of the following definitions is set forth in the Section of this Agreement indicated below:

<u>DEFINITION</u>	<u>SECTION</u>
AAA	10.8(b)
Agreement	Preamble
APA Schedules	5.1(b)
Data Package Delivery Date	4.1(a)
Data Package Review Period	4.2(a)
Dispute	10.8(a)
Effective Date	Preamble
Governmental Filings	5.1(c)
Incyte	Preamble
Incyte Indemnified Party	9.2
Indemnified Party	9.3
Indemnifying Party	9.3
Initial Data Package Delivery Date	3.2(c)(i)
Initial Data Package Review Period	3.2(c)(i)
Option	2.1
Option End Date	4.1(b)
Option Exercise Notice	5.1(a)
Post-Option Exercise Arising IP	5.3(a)(ii)
Post-Option Exercise Inventions	5.3(a)(ii)
Post-Option Exercise Patents	5.3(a)(ii)
Post-Option Exercise V617F Program Activities	5.3(a)
Prelude	Preamble
Prelude Indemnified Party	9.1
Remaining V617F Program Arising IP	5.3(a)(ii)
Rules	10.8(b)

<u>DEFINITION</u>	<u>SECTION</u>
[***] Notice	3.2(c)
[***] Securities Purchase Agreement	3.2(c) Recitals
Target Candidate Profile	3.2(b)
Term	8.1
Upfront Payment	6.1

### 1.63 Interpretation; Construction.

(a) Where a reference in this Agreement is made to a Section or Schedule, such reference shall be to a Section or Schedule to this Agreement unless otherwise indicated.

(b) If a term is defined as one part of speech (such as a noun), it shall have a corresponding meaning when used as another part of speech (such as a verb). The terms defined in the singular have a comparable meaning when used in the plural and vice versa. Unless the context of this Agreement clearly requires otherwise, words importing the masculine gender shall include the feminine and neutral genders and vice versa. Whenever the words “include,” “includes” or “including” are used in this Agreement, they shall be deemed to be followed by the words “without limitation.” The words “hereof,” “herein” and “hereunder” and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The word “or” shall not be exclusive. Currency amounts referenced herein are in U.S. Dollars. Any capitalized term used in any Schedule but not otherwise defined therein shall have the meaning given to them as set forth in this Agreement. All accounting terms used herein and not expressly defined herein shall have the meanings given to them under GAAP. References to “written” or “in writing” include documents in electronic form or transmission by email. A reference to any person includes such person’s successors and permitted assigns.

(c) Except as otherwise specifically provided herein, all references in this Agreement to any Laws include the rules and regulations promulgated thereunder, in each case as amended, re-enacted, consolidated or replaced from time to time and in the case of any such amendment, re-enactment, consolidation or replacement, reference herein to a particular provision shall be read as referring to such amended, re-enacted, consolidated or replaced provision and shall also include, unless the context otherwise requires, all applicable guidelines, bulletins or policies made in connection therewith.

(d) Any contract, agreement or instrument referred to herein means such contract, agreement or instrument as from time to time amended, modified or supplemented, including by waiver or consent and all attachments thereto and instruments incorporated therein.

(e) Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified. Whenever any action must be taken hereunder on or by a day that is not a Business Day, then such action may be validly taken on or by the next day that is a Business Day.

(f) The Parties have drafted this Agreement jointly through the exchange of drafts hereof, so no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provision of this Agreement.

## **ARTICLE II**

### **OPTION**

2.1 **Grant of Exclusive Option.** In consideration for the payment by Incyte to Prelude of the Upfront Payment, subject to the terms and conditions of this Agreement, Prelude hereby grants to Incyte an exclusive option (the “Option”) to acquire all right, title and interest in and to the Transferred Assets in accordance with the terms and conditions of the Asset Purchase Agreement, which option shall be exercisable only during the Option Period and in accordance with the terms and conditions set forth herein. Except for any rights expressly granted hereunder, including the Option as expressly provided in this Section 2.1 and the license for the Post-Option V617F Program Activities granted under Section 5.3(a)(iii), neither Party grants to the other Party any right or license, including any rights or licenses to any Patents, Know-How or other Intellectual Property Rights owned or otherwise controlled by such first Party (or any of its Affiliates), and, for clarity, each Party retains all rights, including all rights under Know-How, Patents and other Intellectual Property Rights owned or otherwise controlled by it (or any of its Affiliates), not expressly granted to the other Party pursuant to this Agreement.

2.2 **Exclusivity.** During the Option Period, Prelude shall not, and shall not permit any of its Affiliates or authorize any of their respective Representatives to, directly or indirectly, (a) solicit, initiate or knowingly encourage, or take any action that would reasonably be expected to facilitate or lead to, any Transaction Proposal; (b) enter into, continue or otherwise participate in any discussions, conversations, negotiations or other communications with, or furnish to or disclose any information to any Person in connection with any Transaction Proposal; **provided**, that any correspondence required to comply with the requirements of the following sentence shall not be considered a breach of the obligations set forth in this clause (b); or (c) enter into any letter of intent, agreement in principle, acquisition agreement, option agreement or other similar agreement with respect to any Transaction Proposal. [\*\*\*].

## **ARTICLE III**

### **V617F PROGRAM; RESEARCH PERIOD**

3.1 **General.** At all times prior to the Closing, (a) the conduct of the V617F Program shall be the sole responsibility of Prelude, (b) as between the Parties, the V617F Assets shall remain owned and controlled by Prelude, and (c) all decision-making related to the V617F Program shall remain with Prelude, in each case, subject to the terms and conditions expressly set forth herein.

#### 3.2 **Research Period.**

(a) Prelude shall (i) use Diligent Efforts to nominate at least one [\*\*\*] and (ii) thereafter use Commercially Reasonable Efforts to deliver the IND Ready Data Package to Incyte, in each case of (i) and (ii), prior to the Option End Date.

(b) Within [\*\*\*] after the Effective Date, the Parties will agree upon the target candidate profile to be satisfied by a V617F Molecule [\*\*\*] in order to be advanced into IND-Enabling Studies (the “Target Candidate Profile”), which profile will be attached hereto as Exhibit D and will be attached as an exhibit to this Agreement and incorporated by reference herein.

(c) During the Option Period, Prelude may provide written notice to Incyte if Prelude determines, in its reasonable discretion, that one or more V617F Molecules [\*\*\*] have satisfied the criteria in the Target Candidate Profile pursuant to the V617F Program [\*\*\*]:

(i) (A) following [\*\*\*], Prelude will prepare and deliver to Incyte the Initial Data Package, in writing or by access to a virtual data room, in a manner reasonably satisfactory to Incyte (such delivery date, the “Initial Data Package Delivery Date”); and (B) Incyte shall have a period of thirty (30) days from the Initial Data Package Delivery Date to review such data and materials (such period, the “Initial Data Package Review Period”);

(ii) promptly following the [\*\*\*] and in any event by the Initial Data Package Delivery Date, the Parties shall enter into a material transfer agreement pursuant to which [\*\*\*]; and

(iii) during the Initial Data Package Review Period, the Parties shall cooperate in good faith to discuss and evaluate [\*\*\*] to determine whether [\*\*\*] should be advanced to IND-Enabling Studies; provided, that, in the event the Parties cannot reach mutual agreement, Prelude shall have final decision-making authority with respect to such advancement (provided that Prelude will consider in good faith Incyte’s comments with respect thereto). [\*\*\*].

3.3 Subcontractors. Prelude may engage its Affiliates or Third Party subcontractors (including contract research organizations and contract manufacturing organizations) to perform portions of its activities under the V617F Program, provided that Prelude shall remain responsible for the performance of such activities by its Affiliates and Third Party subcontractors and the compliance of its Affiliates and Third Party subcontractors with the applicable provisions of this Agreement. Any breach of the terms of this Agreement by an Affiliate or a Third Party subcontractor of Prelude shall constitute a breach of this Agreement by Prelude. Without limiting the foregoing, the use of an Affiliate or Third Party subcontractor by Prelude shall not otherwise relieve Prelude of its obligations under this Agreement.

3.4 Compliance. Prelude shall conduct the V617F Program in a professional manner and in accordance with sound and ethical business and scientific practices, and in compliance with all applicable Laws. Prelude shall not use in any capacity, in connection with the V617F Program, any Person who has ever been, is currently, or is the subject of a proceeding that could lead to such Person becoming a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual. Until the earlier of (a) the end of the Option Period and (b) the execution of the Asset Purchase Agreement, Prelude shall inform Incyte in writing immediately if it or any Person who is performing services for Prelude under the V617F Program becomes or is the subject of a proceeding that could lead to it or such Person becoming a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual.

### 3.5 Intellectual Property Rights.

(a) Invention of all inventions, discoveries, improvements, and other technology discovered, made, conceived, reduced to practice, or created by or on behalf of either Party or any of its Affiliates, or jointly by or on behalf of the Parties or any of their Affiliates, in each case, in the course of conducting the V617F Program hereunder shall be determined in accordance with U.S. patent laws without regard to conflict of law, irrespective of where or when such invention occurs. Subject to Section 5.3(a)(ii), as between the Parties, Prelude shall own and retain all right, title and interest in and to any and all inventions, discoveries, improvements, and other technologies discovered, made, conceived, reduced to practice, or created by or on behalf of either Party or any of its Affiliates, or jointly by or on behalf of the Parties or any of their Affiliates, in each case, in the course of conducting the V617F Program hereunder, whether or not patented or patentable, [\*\*\*]. Incyte hereby assigns and transfers, and agrees to assign and transfer, to Prelude or its designee all of its rights, title and interest in and to all such Patents and Intellectual Property Rights, and agrees to take all further acts reasonably required to evidence such assignments, and Incyte is not acquiring any ownership interest in any such inventions or any such Patents or other Intellectual Property Rights.

(b) Until the earlier of (i) the end of the Option Period and (ii) the execution of the Asset Purchase Agreement, Prelude shall, and shall cause its applicable Affiliates to [\*\*\*] ensure that all employees of Prelude or its Affiliates who may generate, create or develop material Intellectual Property Rights in connection with the V617F Program execute a valid written agreement irrevocably and presently assigning to Prelude or its applicable Affiliate all right, title and interest in and to all Intellectual Property Rights created or developed by such employees in the course of their work. Subject to this Section 3.5, as between the Parties, Prelude shall be solely responsible and have the sole authority and discretion for preparing, filing, prosecuting, maintaining, enforcing and defending all Intellectual Property Rights owned by Prelude, at Prelude's sole expense and using counsel selected by Prelude.

### 3.6 V617F Program Data.

(a) Until the earlier of (i) the end of the Term or (ii) such time as Prelude publishes particular V617F Program Data in accordance with Section 3.6(b), Prelude shall only be permitted to disclose V617F Program Data to Third Parties as follows: [\*\*\*]; provided that, [\*\*\*].

(b) [\*\*\*].

3.7 Reporting. During the Option Period, Prelude shall keep Incyte reasonably informed on a quarterly basis by providing an overview of material developments under the V617F Program, which overview will include (a) any material safety or efficacy issues, adverse findings or adverse events with respect to any V617F Molecule, and (b) notice from any Regulatory Authority of any material concerns regarding any V617F Molecule or any activities under the V617F Program (including the imposition of any hold on, or the requirement or recommendation of the suspension or termination of, any such activities).

3.8 Records. Prelude shall, and shall cause its Affiliates and Third Party subcontractors, as applicable, to, maintain, in accordance with its current practices, complete and accurate records

of (a) all work conducted by such Persons in respect of the V617F Program and all data and other information resulting from such work, and (b) all Regulatory Materials concerning any V617F Molecule or the V617F Program, in each case of (a) and (b), for at least three (3) years following the end of the Option Period (solely to the extent such records are not transferred to Incyte pursuant to the Asset Purchase Agreement). Such records shall fully and properly reflect all work done and results achieved in the performance of the V617F Program in sufficient detail and in a manner that would reasonably be expected to enable use of such documents to seek or challenge Patents with respect to any V617F Molecule or the Manufacture, sale or use thereof or Regulatory Approval of any V617F Molecule.

3.9 Information Share Limitation. [\*\*\*].

3.10 Program Manager. Each Party shall appoint a single individual to act as the primary point of contact between the Parties regarding the V617F Program during the Option Period. Each Party may replace its such appointee at any time by notice in writing to the other Party. Such appointee shall be the first point of referral for all matters hereunder, including potential conflict resolution hereunder.

#### **ARTICLE IV** **DATA PACKAGE; DUE DILIGENCE**

4.1 Data Package Delivery.

(a) Promptly following (and in any event within [\*\*\*] after) the first date on which Prelude has generated all of the data identified on Exhibit B with respect to [\*\*\*], Prelude shall (i) provide written notice to Incyte thereof, and (ii) prepare and deliver to Incyte, in writing or by access to a virtual data room, in a manner reasonably satisfactory to Incyte, (A) the IND Ready Data Package and (B) any then-available data on any other V617F Molecules [\*\*\*] (provided that the applicable data or information is in existence and in the control of Prelude (or any of its Affiliates) as of the time of the Data Package Delivery Date) (such delivery date, the "Data Package Delivery Date").

(b) In the event the IND Ready Data Package will not be ready by the end of the fifteen (15)-month period after the Effective Date, the Option Period shall automatically toll for the period to deliver the IND Ready Data Package; provided that, such tolling shall not exceed an additional three (3)-month period (or any other longer period as mutually agreed to by the Parties) following such fifteen (15)-month period (the last date of such period, the "Option End Date").

4.2 Data Package Review; Due Diligence.

(a) Incyte shall have a period of thirty (30) days after the Data Package Delivery Date (such period, as it may be extended in Section 4.2(b), the "Data Package Review Period") to review the IND Ready Data Package and any other information provided pursuant to Section 4.1(a)(ii).

(b) During the Data Package Review Period, the Parties shall engage in a structured diligence process pursuant to which Prelude shall [\*\*\*] provide to Incyte any information or data in Prelude's or its Affiliates' possession and control, [\*\*\*].

4.3 Due Diligence Prior to IND Ready Data Package. If (a) Incyte notifies Prelude in writing of its interest in potentially exercising the Option at any time prior to the generation by Prelude of the IND Ready Data Package, or (b) no IND Ready Data Package is generated by the Option End Date, [\*\*\*], Prelude shall (i) prepare and deliver to Incyte (solely to the extent existing as of the Option End Date or the date of such written notice from Incyte, as applicable, and then-available to Prelude (in whatever form then existing)) any then-available data (including preclinical, technical, safety and scientific data [\*\*\*] on any V617F Molecules to the extent such data was not previously delivered to Incyte and (ii) [\*\*\*]. In such event, the delivery date for the information specified in the foregoing clause (i) shall constitute the Data Package Delivery Date, and the provisions in Section 4.2 shall apply *mutatis mutandis* (with such information constituting, for the purposes of Section 4.2, the IND Ready Data Package).

## **ARTICLE V** **OPTION EXERCISE**

### 5.1 Option Exercise Notice

(a) Incyte shall have the right, in its sole discretion, to exercise the Option at any time during the Option Period by delivering to Prelude a written notice of such election to exercise the Option (the "Option Exercise Notice"). For clarity, Incyte's right to exercise the Option shall not be contingent upon, and may be exercised prior to, achievement of [\*\*\*] or delivery of the IND Ready Data Package.

(b) Within [\*\*\*] of the delivery of the Option Exercise Notice, Prelude shall deliver to Incyte (i) a set of disclosure schedules ("APA Schedules") (A) with respect to Prelude's representations, warranties and covenants under the Asset Purchase Agreement and (B) setting forth a complete list of Transferred Contracts, Transferred Know-How and Transferred Patents (in each case, as such terms are defined in the Asset Purchase Agreement), and (ii) copies of all documents referenced in the APA Schedules to the extent not previously provided. Prelude shall [\*\*\*] make available any information [\*\*\*]. If Incyte delivers the Option Exercise Notice in accordance with this Agreement, then the Parties shall execute the Asset Purchase Agreement as promptly as practicable, and in any event, within [\*\*\*] of delivery of the Option Exercise Notice.

(c) Incyte shall, after good faith consultation with Prelude, determine whether a filing under the HSR Act or any other consents, clearances, registrations, approvals, permits and authorizations are necessary or advisable to be obtained from any Governmental Authority (collectively, "Governmental Filings") in order to consummate the transactions contemplated by the Asset Purchase Agreement, and shall notify Prelude of such determination within [\*\*\*] of delivery of the Option Exercise Notice. The Parties shall each, upon request by the other, promptly furnish the other with all information concerning itself, its Subsidiaries, directors, officers and members and stockholders and such other matters as may be reasonably necessary or advisable (x) in connection with making such determination as to whether any Governmental Filings are necessary and (y) in connection with any statement, filing, notice or application made by or on

behalf of Prelude, Incyte or any of their respective Subsidiaries to any Governmental Authority in connection with the transactions contemplated by the Asset Purchase Agreement, and to the extent Incyte determines that any Governmental Filings are necessary, the Parties shall, during the period after Incyte notifies Prelude thereof and prior to execution of the Asset Purchase Agreement, prepare all documentation necessary to make such Governmental Filings as promptly as practicable, and in any event, within [\*\*\*] following execution of the Asset Purchase Agreement. For the avoidance of doubt, the filing deadlines and the Parties' obligations in connection with any Governmental Filings shall be governed by the executed Asset Purchase Agreement.

5.2 Expiration of Option. If Incyte does not deliver the Option Exercise Notice by 5:00 p.m. Eastern Time on the last day of the Option Period, then this Agreement shall expire.

5.3 Post-Option Exercise V617F Program Activities.

(a) In the event that Incyte exercises the Option prior to the Option End Date, then notwithstanding anything to the contrary contained herein (or in the Asset Purchase Agreement entered into by the Parties), Prelude shall have the right, in its sole discretion and at its sole cost, to continue to conduct the V617F Program in order to [\*\*\*] (the "Post-Option Exercise V617F Program Activities"), and in connection therewith the following shall apply, in each case, until the earlier of (x) the termination of the Asset Purchase Agreement in accordance with Section 6.1 thereof or (y) the Option End Date:

(i) the provisions of Section 3.2(c) shall survive and continue in full force and effect (notwithstanding the exercise of the Option or the expiration or termination of this Agreement) with respect to the performance of Post-Option Exercise V617F Program Activities, including that, for clarity, prior to the Option End Date, (A) Prelude may provide written notice to Incyte if Prelude determines, in its sole discretion, that one or more V617F Molecules [\*\*\*] have satisfied the criteria in the Target Candidate Profile pursuant to Prelude's V617F Program (and each such V617F Molecules shall be [\*\*\*]) and (B) in the event the Parties (or Prelude in the exercise of its final decision-making authority) determine that any [\*\*\*];

(ii) as between the Parties, all inventions, data, discoveries, improvements, and other technology discovered, made, conceived, reduced to practice, or created by or on behalf of either Party or any of its Affiliates, or jointly by or on behalf of the Parties or any of their Affiliates, in each case, in the course of conducting the Post-Option Exercise V617F Program Activities ("Post-Option Exercise Inventions"), together with all Patents claiming a Post-Option Exercise Invention ("Post-Option Exercise Patents") and any other Intellectual Property Rights in any Post-Option Exercise Invention ("Post-Option Exercise Arising IP") and collectively with Post-Option Exercise Inventions and Post-Option Exercise Patents, "Remaining V617F Program Arising IP", will be [\*\*\*]; and

(iii) if the performance of the Post-Option Exercise V617F Program Activities by Prelude and its Affiliates would, in the absence of a license from Incyte or its Affiliates, infringe, misappropriate or otherwise violate any Intellectual Property Rights that are owned or controlled by Incyte or its Affiliates and are licensable or sublicensable, as applicable, to Prelude and its Affiliates for the performance of the Post-Option Exercise V617F Program Activities without any Third Party consent or the payment of any additional consideration, Incyte,

on behalf of itself and its Affiliates, hereby grants to Prelude and its Affiliates a non-exclusive, revocable, non-transferable, non-sublicensable, worldwide, royalty-free, fully paid-up license or sublicense, as applicable, under such Intellectual Property Rights, solely to the extent and for the duration necessary for Prelude and its Affiliates to perform the Post-Option Exercise V617F Program Activities.

(b) Notwithstanding the provisions of Section 5.3(a), in the event that any Post-Option Exercise V617F Program Activities are being conducted as of the Option End Date, then Prelude shall wind-down such V617F Program Activities in a reasonably prompt manner.

## **ARTICLE VI FINANCIAL PROVISIONS**

6.1 Upfront Payment. In consideration for the Option, Incyte shall pay to Prelude a nonrefundable and noncreditable upfront payment in an amount equal to Thirty-Five Million Dollars (USD 35,000,000) (the “Upfront Payment”) within five (5) Business Days after the later of (a) the Effective Date and (b) delivery by Prelude to Incyte of a duly executed I.R.S. Form W-9, by wire transfer of immediately available funds to an account specified by Prelude.

6.2 Equity Investment. Concurrently with entry into this Agreement, Incyte will purchase \$25,000,000 of shares of non-voting common stock of Prelude pursuant to the terms and conditions set forth in the Securities Purchase Agreement.

## **ARTICLE VII REPRESENTATIONS, WARRANTIES AND COVENANTS**

7.1 Representations and Warranties of Prelude. Prelude represents and warrants to Incyte as of the Effective Date as follows:

(a) Organization; Good Standing. Prelude is duly organized, validly existing and in good standing under the Laws of the jurisdiction of its organization. Prelude has the requisite power and authority to carry on its Business as currently conducted.

(b) Authority; Execution and Delivery. Prelude has the requisite corporate power and authority to enter into this Agreement and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement by Prelude and the consummation of the transactions contemplated hereby have been duly and validly authorized. This Agreement has been duly executed and delivered by Prelude and, assuming the due authorization, execution and delivery of this Agreement by Incyte, will constitute the legal, valid and binding obligation of Prelude, enforceable against it in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other similar Laws affecting creditors’ rights generally from time to time in effect and to general principles of equity (including concepts of materiality, reasonableness, good faith and fair dealing), regardless of whether considered in a proceeding in equity or at Law.

(c) Consents; No Violation. The execution and delivery of this Agreement, and the consummation of the transactions contemplated hereby and thereby and the compliance with

the terms hereof and thereof will, not (i) violate any Laws applicable to Prelude or the V617F Assets in any material respect, (ii) conflict with any provision of the certificate of incorporation or by-laws (or similar organizational document) of Prelude, (iii) conflict with any material contract to which Prelude or any of its Affiliates is a party or by which it is otherwise bound, including any contract (whether or not material) related to the V617F Assets, or (iv) require any approval, authorization, consent, license, exemption, filing or registration with any court, arbitrator or Governmental Authority, except in the case of the immediately preceding clauses (iii) and (iv) to the extent that any such violation, breach, default, termination or consent would not reasonably be expected to have, individually or in the aggregate, a would not have a material adverse effect on Incyte's ability to consummate the transactions contemplated hereby.

(d) Title to V617F Assets. Prelude has good and valid title to all V617F Assets, free and clear of all Encumbrances, other than Permitted Encumbrances.

(e) Regulatory Matters. Prelude has not filed or obtained any INDs, Drug Approval Applications or any other regulatory documentation for any V617F Molecules in any jurisdiction.

(f) No Brokers. Prelude has not entered into any contract, agreement, arrangement or understanding with any corporation, person, partnership, entity or firm (irrespective of legal form and jurisdiction of organization) which will result in the obligation to pay any finder's fee, brokerage commission or similar payment in connection with the transactions contemplated hereby.

## 7.2 Representations and Warranties of Incyte. Incyte hereby represents and warrants to Prelude as follows:

(a) Organization; Good Standing. Incyte is duly organized, validly existing and in good standing under the Laws of the State of Delaware. Incyte has the requisite corporate power and authority to carry on its business as it is currently being conducted.

(b) Authority; Execution and Delivery. Incyte has the requisite corporate power and authority to enter into this Agreement and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly and validly authorized. This Agreement has been duly executed and delivered by Incyte and, assuming the due authorization, execution and delivery of this Agreement by Prelude, constitutes the legal, valid and binding obligation of Incyte, enforceable against Incyte in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other similar Laws affecting creditors' rights generally from time to time in effect and to general principles of equity (including concepts of materiality, reasonableness, good faith and fair dealing), regardless of whether considered in a proceeding in equity or at Law.

(c) Consents; No Violations. The execution and delivery of this Agreement, and the consummation of the transactions contemplated hereby and thereby and the compliance with the terms hereof and thereof will, not (i) violate any Laws applicable to Incyte in any material respect, (ii) conflict with any provision of the certificate of incorporation or by-laws of Incyte, (iii)

conflict with any material contract to which Incyte is a party or by which it is otherwise bound or (iv) require any approval, authorization, consent, license, exemption, filing or registration with any court, arbitrator or Governmental Authority, except in the cases of clause (iii), where the violation, breach, conflict, default, acceleration, or failure to give notice would not have a material adverse effect on Incyte's ability to consummate the transactions contemplated hereby.

(d) No Brokers. Incyte has not entered into any agreement, arrangement or understanding with any Person or firm which will result in the obligation to pay any finder's fee, brokerage commission or similar payment in connection with the transactions contemplated hereby.

7.3 [\*\*\*].

7.4 Disclaimer; No Warranty. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, (A) THE V617F ASSETS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE THEREOF WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY, AND (B) NEITHER PARTY HERETO MAKES ANY REPRESENTATION AND EXTENDS NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED. IN PARTICULAR, BUT WITHOUT LIMITATION, PRELUDE MAKES NO REPRESENTATION AND EXTENDS NO WARRANTY CONCERNING WHETHER THE V617F ASSETS ARE FIT FOR ANY PARTICULAR PURPOSE OR SAFE FOR HUMAN CONSUMPTION.

## **ARTICLE VIII TERM AND TERMINATION**

8.1 Term. This Agreement shall become binding and effective as of the Effective Date, and, unless earlier terminated pursuant to this ARTICLE VIII, shall remain in effect until 5:00 p.m. Eastern Time on the last day of the Option Period (provided if Incyte delivers the Option Exercise Notice to Prelude prior to such time in accordance with the terms and conditions of this Agreement, then unless earlier terminated pursuant to this ARTICLE VIII, this Agreement shall remain in effect until the execution of the Asset Purchase Agreement pursuant to Section 5.1(b)) (the "Term").

8.2 Termination. This Agreement may be terminated at any time:

(a) by written agreement of the Parties; and

(b) by Incyte, by written notice to Prelude, at any time during the Option Period and prior to the delivery of the Option Exercise Notice, if Incyte shall determine in its sole discretion that it does not wish to exercise the Option; and

(c) by Prelude upon written notice at any time during the Term upon or after a material breach of this Agreement by Incyte [\*\*\*], if Incyte has not cured such breach within [\*\*\*] following receipt of written notice from Prelude requesting cure of the breach.

8.3 Effects of Termination. In the event of termination (but not expiration) of this Agreement:

(a) Notwithstanding anything contained herein to the contrary, all rights and licenses (including the Option) granted to Incyte hereunder will terminate and will revert back to Prelude; and

(b) Incyte shall promptly return to Prelude, or destroy (at Prelude's written request), all documents, and copies thereof, containing Confidential Information of Prelude, together with all notes, drawings, abstracts and other information relating to Prelude's Confidential Information prepared by Incyte or any of its Representatives, regardless of the medium in which such information is stored; provided, however, that Incyte may retain one (1) copy of such documents in a secure location for compliance purposes.

8.4 Survival. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination of this Agreement, and the provisions of Section 5.3 (solely for the period set forth therein), this Section 8.4 and ARTICLE X shall survive the expiration or termination of this Agreement. Any expiration or early termination of this Agreement will be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to termination. The termination provisions of this ARTICLE VIII are in addition to any other relief and remedies available to either Party under this Agreement and under applicable Law.

## **ARTICLE IX** **INDEMNIFICATION**

9.1 By Incyte. Incyte shall indemnify, defend, hold harmless and reimburse Prelude, its Affiliates, and their respective directors, officers, agents, employees, successors and assigns (each, a "Prelude Indemnified Party") for, from and against any and all claims, obligations and other Losses asserted by a Third Party arising out of, relating to, or occurring as a result of or in connection with: (a) any breach by Incyte of any of its representations, warranties, or obligations pursuant to this Agreement; or (b) the gross negligence or willful misconduct of Incyte; provided that Incyte shall not indemnify, defend nor hold harmless Prelude Indemnified Parties from and against any claims, obligations and other Losses arising out of, relating to, or occurring as a result of or in connection with any claim to the extent that Prelude is obligated to defend, indemnify or hold harmless the Incyte Indemnified Parties pursuant to Section 9.2.

9.2 By Prelude. Prelude shall indemnify, defend, hold harmless and reimburse Incyte, its Affiliates, and their respective directors, officers, agents, employees, successors and assigns (each, an "Incyte Indemnified Party") for, from and against any and all claims, obligations and other Losses asserted by a Third Party arising out of, relating to, or occurring as a result of or in connection with: (a) any breach by Prelude of any of its representations, warranties, or obligations pursuant to this Agreement; or (b) the gross negligence or willful misconduct of Prelude; provided that Prelude shall not indemnify, defend nor hold harmless Incyte Indemnified Parties from and against any claims, obligations and other Losses arising out of, relating to, or occurring as a result of or in connection with any claim to the extent that Incyte is obligated to defend, indemnify or hold harmless the Prelude Indemnified Parties pursuant to Section 9.1.

9.3 Procedure. If either Party is seeking indemnification under Sections 9.1 and 9.2 (the “Indemnified Party”), it will inform the other Party (the “Indemnifying Party”) of the suit or claim giving rise to the obligation to indemnify pursuant to such Section as soon as reasonably practicable after receiving notice of the claim (provided, however, any delay or failure to provide such notice will not constitute a waiver or release of, or otherwise limit, the Indemnified Party’s rights to indemnification under, as applicable, Sections 9.1 and 9.2, except to the extent that such delay or failure materially prejudices the Indemnifying Party’s ability to defend against the relevant claims). The Indemnifying Party will have the right to assume the defense of any suit or claim if it has assumed responsibility for the suit or claim in writing. The Indemnified Party will cooperate with the Indemnifying Party and the Indemnifying Party’s insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party’s cost and expense. The Indemnified Party will have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the Indemnifying Party; provided that, if the Indemnifying Party assumes control of such defense and the Indemnified Party reasonably concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such suit or claim, the Indemnifying Party shall be responsible for the reasonable fees, costs and expenses of counsel to the Indemnified Party solely in connection therewith; provided, further, however, that in no event shall the Indemnifying Party be responsible for the fees, costs and expenses of more than one counsel in any one jurisdiction for all Indemnified Parties. The Party controlling such defense shall keep the other Party advised of the status of such suit or claim and the defense thereof and shall consider in good faith recommendations made by the other Party with respect thereto. The Indemnifying Party will not settle any suit or claim in any manner which would have an adverse effect on the Indemnified Party’s interests without the prior written consent of the Indemnified Party, which consent shall not to be unreasonably withheld, conditioned or delayed if the settlement or compromise would impose no financial or other obligations or burdens on, or include an admission by, the Indemnified Party. The Indemnified Party will not settle or compromise any such claim without the prior written consent of the Indemnifying Party, which it may provide in its sole discretion.

9.4 General Limitation of Liability. EXCEPT WITH RESPECT TO A PARTY’S (A) LIABILITY PURSUANT TO SECTION 9.1 OR SECTION 9.2 OR (B) WILLFUL MISCONDUCT OR GROSS NEGLIGENCE, NEITHER PARTY SHALL BE LIABLE FOR SPECIAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE OR OTHER INDIRECT OR REMOTE DAMAGES, OR FOR LOSS OF PROFITS OR BUSINESS INTERRUPTION, LOSS OF DATA OR LOSS OF USE DAMAGES, IN EACH CASE ARISING IN ANY WAY OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSS.

9.5 Insurance. Prelude shall maintain Third Party insurance and/or self-insurance, as applicable, including product liability insurance, with respect to its activities hereunder in amounts customary to such insurance and sufficient to meet its obligations under this Agreement, and shall claim upon such insurance policy according to such policy’s relevant terms and conditions before relying upon indemnification from Incyte.

**ARTICLE X**  
**MISCELLANEOUS**

10.1 Confidentiality.

(a) The terms of the Confidentiality Agreements are hereby incorporated by reference, *mutatis mutandis*, and shall continue in full force and effect in accordance with their terms.

(b) Except as required by judicial order or applicable Law, including the rules and regulations promulgated by the SEC or any other Governmental Authority, or by the requirements of a securities exchange on which the securities of either Party (or any of its Affiliates) are listed, neither Party shall make any public announcement concerning, or otherwise disclose the terms of, this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. The Party preparing any such public announcement shall provide the other Party with a draft thereof at least ten (10) Business Days prior to the date on which such Party would like to make the public announcement. The Parties will cooperate in good faith to prepare and agree upon the text of a joint press release announcing the transactions contemplated by this Agreement prior to the execution of this Agreement. Such mutually agreed press release will be issued promptly following execution of this Agreement at a time coordinated by the Parties.

10.2 Assignment. This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective successors and permitted assigns. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party; provided, that, notwithstanding the foregoing, either Party may, without consent of the other Party, assign this Agreement and its rights and obligations hereunder (a) in whole or in part to an Affiliate of such Party; provided, further, that such Party will remain liable for all of its rights and obligations under this Agreement; and provided, further, that such assignee Affiliate shall assign this Agreement back to the original Party at any future date that such assignee is no longer an Affiliate of such Party or (b) in whole to a successor entity in a Change of Control of such Party; provided, further, that in the case of the foregoing clause (b), the assigning Party provides written notice of such assignment to the non-assigning Party within 10 days after the effective date of such assignment and the assignee will expressly agree to be bound in writing by such Party's obligations under this Agreement. Any attempted assignment of this Agreement not in accordance with this Section 10.2 will be null, void, and of no legal effect. Any permitted assignee will assume all assigned obligations of its assignor under this Agreement. The terms and conditions of this Agreement will be binding upon, and will inure to the benefit of, the Parties and their respected successors and permitted assigns.

10.3 Disposition of Program. [\*\*\*].

10.4 Amendment and Modification; Waiver. This Agreement may only be amended, modified or supplemented by an agreement in writing signed by each Party hereto. No waiver by any Party of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the Party so waiving. No waiver by any Party shall operate or be construed as a

waiver in respect of any failure, breach or default not expressly identified by such written waiver, whether of a similar or different character, and whether occurring before or after that waiver. No failure to exercise, or delay in exercising, any right, remedy, power or privilege arising from this Agreement shall operate or be construed as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.

10.5 Expenses. Except as otherwise expressly provided in this Agreement, all costs and expenses, including fees and disbursements of counsel, financial advisors and accountants, incurred in connection with this Agreement and the transactions contemplated hereby shall be paid by the Party incurring such costs and expenses.

10.6 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Laws, and if the rights or obligations of either Party under this Agreement shall not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance here from, and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties herein.

10.7 Governing Law. This Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, regardless of the Laws that might otherwise govern under applicable principles of conflicts of laws thereof.

#### 10.8 Dispute Resolution and Venue.

(a) If any dispute, controversy, or claim arises out of or relates to this Agreement, including its existence, validity, breach, termination, or interpretation (a “Dispute”), either Party may deliver written notice describing the Dispute in reasonable detail. The Parties’ Executive Officers shall diligently and in good faith attempt to resolve the referred Dispute within thirty (30) days after such notice (or such longer period as the Executive Officers may agree in writing). Any final decision mutually agreed to by the Executive Officers and set forth in writing shall be conclusive and binding on the Parties.

(b) If the Dispute is not resolved within thirty (30) days after the notice under 10.8(a), such Dispute shall be settled by arbitration administered by the American Arbitration Association (“AAA”) under its Commercial Arbitration Rules (the “Rules”) and the procedures set forth in this Section 10.8(b). In the event of any inconsistency between the Rules and this Section 10.8, the provisions of this Section 10.8 shall control. The arbitration shall be conducted in Wilmington, Delaware, in the English language, by a panel of three (3) neutral arbitrators who are independent and disinterested with respect to the Parties, this Agreement, and the outcome of the arbitration. Each Party shall appoint one (1) neutral arbitrator, and those two (2) arbitrators shall then select the third arbitrator, who shall serve as chair. All arbitrators must have at least fifteen (15) years’ experience in the biopharmaceutical industry and in mediating or arbitrating

cases regarding the same or substantially similar subject matter as the Dispute. If one Party gives written notice of its appointed arbitrator and the other Party fails to appoint its arbitrator within ten (10) days after a written demand to do so, the arbitrator already appointed shall appoint the remaining two (2) arbitrators. Either Party may seek emergency relief under the Rules (including the Optional Rules for Emergency Measures of Protection). The tribunal may grant interim or conservatory measures it deems appropriate, including specific performance and injunctive relief, and shall issue a reasoned award within nine (9) months after its constitution, absent good cause. The arbitration and all related materials, submissions, evidence, and awards shall be treated as confidential information under Confidentiality Agreements and disclosed only to the tribunal, the AAA, the Parties and their Representatives with a need to know (subject to obligations of confidentiality), or as required by Law or to enforce, challenge, or defend the award. The fees of the arbitrators and costs and expenses of the arbitration shall be borne as allocated by the tribunal, which may award costs and fees, including AAA fees, arbitrator compensation, and reasonable attorneys' fees, to the prevailing Party as it deems appropriate. Judgment upon the award rendered by the tribunal may be entered in any court of competent jurisdiction. Nothing in this Section 10.8 limits either Party's right to seek temporary, preliminary, or injunctive relief or specific performance from a court of competent jurisdiction to preserve the status quo or prevent irreparable harm pending arbitration, or to confirm, enforce, correct, or vacate an arbitral award.

(c) Notwithstanding anything to the contrary, either Party may seek immediate injunctive or other interim relief from any court of competent jurisdiction as necessary to enforce the provisions in Section 10.1(a) and to enforce and prevent infringement or misappropriation of the Patent rights, Know-How or Confidential Information controlled by such Party.

10.9 Notices. Any and all notices and communications under this Agreement shall be made in writing in the English language and delivered by hand, courier, telefax, or email to the Person at the address set forth below, or such other Person or address as may be designated by the respective Party to the other Party in the same manner:

if to Incyte:

Incyte Corporation  
1801 Augustine Cut-off  
Wilmington, DE 19803  
United States

Attn. [\*\*\*]  
Email: [\*\*\*]

with a copy to (which copy shall not constitute notice hereunder):

Sullivan & Cromwell LLP  
125 Broad Street  
New York, NY 10004  
United States

Attn.: Matthew Hurd, Rachel Yu and Mimi Wu  
Email: hurdm@sullcrom.com, yuru@sullcrom.com, wum@sullcrom.com

if to Prelude:

Prelude Therapeutics Incorporated  
175 Innovation Boulevard  
Wilmington, DE 19803

Attn.: Chief Legal Officer  
Email: legal@preludetx.com

with a copy to (which copy shall not constitute notice hereunder):

Morgan Lewis & Bockius LLP  
2222 Market Street  
Philadelphia, PA 19103-3007

Attn.: Richard B. Aldridge and Andrew Haupt  
Email: richard.aldridge@morganlewis.com; andrew.haupt@morganlewis.com

10.10 Entire Agreement. This Agreement contains the entire understanding, whether oral or written, of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, whether oral or written, heretofore made are expressly superseded by this Agreement.

10.11 Further Assurances. The Parties shall, and shall cause their respective Affiliates to, promptly execute and deliver all documents, certificates, agreements and other writings and take all actions required to consummate, implement, effectuate, perfect, confirm or record the transactions contemplated by this Agreement.

10.12 No Third-Party Beneficiaries. Except as expressly provided herein, this Agreement is for the sole benefit of the Parties hereto and their respective successors and permitted assigns and nothing herein, express or implied, is intended to or shall confer upon any other Person or entity any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

10.13 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. If any signature is delivered by facsimile transmission or by e-mail delivery of a "PDF" format data file, such signature shall create a valid and binding obligation of the Party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or "PDF" signature page were an original thereof, provided that such facsimile or "PDF" signature is confirmed by an original signature.

{Signature Page Follows}

IN WITNESS WHEREOF, the Parties have caused their duly authorized officers to execute and acknowledge this Agreement as of the date first written above.

**Prelude Therapeutics Incorporated**

By: /s/ Kris Vaddi  
Name: Kris Vaddi, Ph.D.

Title: Chief Executive Officer

**Incyte Corporation**

By: /s/ William Meury  
Name: William Meury

Title: President and CEO

*[Signature Page to Exclusive Option Agreement]*

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**EXHIBIT A**  
**FORM OF ASSET PURCHASE AGREEMENT**

*[see attached]*

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**Exhibit A**

**Form of  
ASSET PURCHASE AGREEMENT**

**by and between  
PRELUDE THERAPEUTICS INCORPORATED  
and  
INCYTE CORPORATION**

**Dated as of [●]**

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**List of Schedules and Exhibits**

Exhibit A – Assignment and Assumption and Bill of Sale Agreement

Exhibit B – Patent Assignment Agreement

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Company Schedules

## **ASSET PURCHASE AGREEMENT**

This ASSET PURCHASE AGREEMENT (including the exhibits and schedules hereto, each as amended or restated from time to time, this “Agreement”), dated as of [●] (the “Execution Date”), is made by and between Prelude Therapeutics Incorporated, a Delaware corporation (“Prelude”), and Incyte Corporation, a Delaware corporation (“Incyte”) (each of Prelude and Incyte, a “Party”, and collectively, the “Parties”).

### **RECITALS**

**WHEREAS**, Incyte and Prelude have entered into that certain Research and Exclusive Option Agreement, dated as of November 2, 2025 (the “Option Agreement”), pursuant to which Incyte was granted an exclusive option to acquire Prelude’s entire right, title and interest in and to the Transferred Assets, and Incyte has exercised such option under the Option Agreement; and

**WHEREAS**, subject to the terms hereof, Prelude desires to sell, transfer, assign, deliver and convey to Incyte, and Incyte desires to purchase, acquire and accept from Prelude, Prelude’s entire right, title and interest in and to the Transferred Assets, and Incyte has agreed to assume the Assumed Liabilities (as defined below) as of the Closing Date, and take the related actions contemplated hereby.

**NOW, THEREFORE**, in consideration of the premises, and of the representations, warranties, covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

### **ARTICLE I DEFINITIONS**

Section 1.1 Definitions. As used in this Agreement, the following terms shall have the meanings set forth below unless otherwise specified herein or context requires otherwise:

“Accounting Standards” means U.S. GAAP (United States Generally Accepted Accounting Principles) or IFRS (International Financial Reporting Standards), as applicable.

“Action” means any action, suit, claim, complaint, litigation, investigation, audit, proceeding, arbitration or other similar dispute.

“Affiliate” means with respect to a Party, any entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. For this purpose, “control” means the ownership of 50% or more of the voting securities entitled to elect the directors or management of the entity, or the actual power to elect or direct the management or policies of the entity, whether by law, contract or otherwise.

“Allocation Dispute Notice” has the meaning set forth in Section 4.9(c).

“Allocation Schedule” has the meaning set forth in Section 4.9(c).

“Assignment and Assumption and Bill of Sale Agreement” means the Assignment and Assumption and Bill of Sale Agreement between Prelude, on the one hand, and Incyte, on the other hand, in substantially the form attached hereto as Exhibit A.

“Business” means the research, Development, Manufacture, use, Regulatory Activities, Commercialization or other exploitation of the V617F Molecules anywhere in the world.

“Business Day” means any day except Saturday, Sunday and any day on which banking institutions in New York, New York or Wilmington, Delaware generally are closed as a result of federal, state or local holiday.

“Change” means any change, occurrence, development, circumstance, fact or effect.

“Change of Control” means, with respect to either Party, the occurrence of any of the following after the Closing Date: (a) the acquisition by a Third Party, in one transaction or a series of related transactions, of direct or indirect beneficial ownership of more than 50% of the outstanding voting equity securities of such Party; (b) a merger, reorganization or consolidation involving such Party, as a result of which a Third Party acquires direct or indirect beneficial ownership of more than 50% of the voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a sale of all or substantially all of the assets of such Party or all or substantially all of the assets to which this Agreement relates in one transaction or a series of related transactions to a Third Party. The acquiring or combining Third Party in any of (a), (b) or (c), and any of such Third Party’s Affiliates (whether in existence as of or any time following the applicable transaction, but other than the acquired Party and its Affiliates as in existence prior to the applicable transaction) are referred to collectively herein as the “Acquirer”.

Notwithstanding the foregoing, (a) a sale of capital stock to new or existing investors of a Party in a private placement, in each case, solely for the purpose of a bona fide financing, and (b) changing the form or jurisdiction of organization of such Party, will not be deemed a “Change of Control” for purposes of this Agreement.

“Closing Cash Consideration” means an amount in cash equal to \$100,000,000.

“Commercialize”, “Commercialization” or “Commercializing” means any activities directed toward maintaining Regulatory Approvals, obtaining and maintaining pricing or reimbursement approvals, marketing, promoting, distributing, importing, offering to sell, or selling a product (including establishing the price for such product).

“Commercially Reasonable Efforts” means, with respect to the efforts to be expended by Incyte, the reasonable, diligent, good-faith efforts that a prudent biopharmaceutical company of comparable size and resources would devote to achieve the specified objective, it being understood and agreed that, with respect to efforts to be expended in relation to any V617F Molecules or Products, as applicable, such efforts shall be substantially consistent with those efforts and resources commonly used by a prudent biopharmaceutical company of comparable size and resources for any other product owned by it or in relation to which it may have rights [\*\*\*]. Commercially Reasonable Efforts shall be determined on a market-by-market and Indication-by-Indication basis for a particular Product, and it is anticipated that the level of effort will be different for different markets and will change over time, reflecting, among other things, changes in the status of the Product and the market(s) involved and shall not exclude the possibility of terminating Development or Commercialization of a particular V617F Molecule or Product.

“Confidential Information” means, with respect to a Party, any and all confidential or proprietary documents, technology, Know-How or other information (whether or not patentable) actually disclosed by or on behalf of one Party or any of its Affiliates to the other pursuant to this Agreement or the Confidentiality Agreements, which may include specifications, Know-How, trade secrets, technical information, models, business information, inventions, discoveries, methods, procedures, formulae,

protocols, techniques, data, and unpublished Patent applications, whether disclosed in oral, written, graphic, or electronic form; provided that Confidential Information does not include any information that (a) is or becomes publicly available through no breach of this Agreement by the receiving Party or its Representatives; (b) was rightfully known to the receiving Party or its Representatives, without confidentiality restrictions, prior to disclosure by the disclosing Party; (c) is independently developed by the receiving Party or its Representatives without use of or reference to any Confidential Information of the disclosing Party; or (d) is rightfully obtained by the receiving Party from a Third Party who, to the receiving Party's knowledge, is not under a duty of confidentiality with respect to such information.

“Confidentiality Agreements” means (a) the Mutual Confidential Disclosure Agreement, dated as of March 3, 2022, by and between Prelude and Incyte, as amended on February 9, 2024 and December 17, 2024, and (b) the Clean Team Agreement, dated as of March 3, 2025, by and between Prelude and Incyte, as amended on October 7, 2025 and October 8, 2025.

“Consideration” has the meaning set forth in Section 4.9(c).

“Cover”, “Covering” or “Covered” means, with respect to a product, technology, process or method, that, but for a license granted to a Person under a claim included in the Patents under which such license is granted, the Development, Manufacture, Commercialization, importation, or other use of such product or the practice of such technology, process, or method by such Person would infringe such claim (or, in the case of a claim that has not yet issued, would infringe such claim if it were to issue).

“Data / Market Exclusivity” means on a Product-by-Product and country-by-country basis, the ability to exclude Third Parties from Commercializing a Product in a country conferred by a Regulatory Authority in such country, either through data exclusivity rights, orphan drug designation, or other similar rights other than through Patent rights.

“Develop” or “Development” means any and all (a) activities related to the design, discovery, generation, identification, profiling, selection, optimization, characterization, process science, formulation and manufacturing process development, pre-clinical development or non-clinical or pre-clinical studies of drug candidates, products and components thereof, including manufacturing in support thereof, and (b) activities related to test method development and stability testing, toxicology, formulation and manufacturing process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical trials (conducted before and after Regulatory Approval), including manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining, maintaining or expanding a Regulatory Approval. For clarity, “Develop” and “Development” shall include any submissions and activities required by applicable Laws or a Regulatory Authority as a condition or in support of obtaining a pricing or reimbursement approval for an approved product.

“Development Candidate” means [\*\*\*] any other V617F Molecule that has been identified and synthesized by Prelude or any of its Affiliates prior to the Option End Date (as such term is defined in the Option Agreement) and set forth on Section 1.1 of the Company Schedules, which schedule will be updated by the Parties following the Option End Date ([\*\*\*]).

“Drug Approval Application” means (a) a New Drug Application (as defined in the U.S. Federal Food, Drug and Cosmetics Act and the regulations promulgated thereunder (21 C.F.R. §312)) or (b) a Biologics License Application (as more fully described in 21 C.F.R. § 601.20 or its successor regulation),

including all supplements, amendments, variations, extensions and renewals of any such application and any application for approval under the FDA accelerated approval program (“Accelerated Approval”).

“Encumbrance” means any lien, pledge, hypothecation, mortgage, security interest, encumbrance, right of first refusal, preemptive right or similar restriction of any nature.

“Excluded Assets” means any asset, property or right of any kind, nature, character or description (whether real personal or mixed, whether tangible or intangible, whether absolute, accrued, contingent, fixed or otherwise, and wherever situated) that is not included within the definition of Transferred Assets, including (i) all right, title and interest in and to the corporate names and logos of Prelude and its Affiliates, (ii) the employment of any person who is an employee of Prelude or any of its Affiliates on the Closing Date, (iii) any accounts receivable relating to the Transferred Assets accrued as of or prior to the Closing Date (whether or not recorded on the books and records of Prelude or any of its Affiliates prior to the Closing Date), (iv) all cash and cash equivalents of Prelude and its Affiliates, (v) the corporate seals, organizational documents, minute books, stock books, books of account or other records having to do with the corporate organization of Prelude or its Affiliates and all employee-related or employee benefit-related files or records, (vi) all insurance policies of Prelude and its Affiliates and all rights to applicable claims and proceeds thereunder, (vii) all Tax Returns of Prelude and its Affiliates and financial statements and records (including work papers) related thereto, (viii) all rights to any Action of any nature available to or being pursued by Prelude or its Affiliates, whether arising by way of counterclaim or otherwise, except any Action Related to the Business, (ix) all websites, URLs and domain names, and (x) all permits, licenses, franchises, approvals, authorizations and consents issued by any Governmental Authority that are not Related to the Business.

“Excluded Liabilities” means any Liabilities of Prelude or any of its Affiliates other than the Assumed Liabilities, including:

- (a) any Liabilities related to the Excluded Assets;
- (b) any Liabilities to the extent arising from a Transferred Contract [or a Relevant Part of a Commingled Contract] that were required to be fully performed prior to the Closing Date, as applicable, or any defaults or breaches of such Transferred Contracts [or the Relevant Part of such Commingled Contracts] by Prelude or any of its Affiliates occurring prior to the Closing Date; provided that such Liabilities will exclude any amounts attributable to acts or omissions of Incyte or its Affiliates after the Closing;<sup>1</sup>
- (c) any Liabilities arising out of any contract entered into by Prelude or any of its Affiliates that is [neither][not] a Transferred Contract [nor, after assignment thereof, the Relevant Part of a Commingled Contract];
- (d) any Liabilities to the extent arising out of any violations of Laws by Prelude or any of its Affiliates to the extent related to the Transferred Assets or Related to the Business that occurred prior to the Closing Date (and not resulting from any post-Closing acts or omissions by Incyte or its Affiliates);
- (e) any Liabilities to the extent directly resulting from any Action, regardless of when commenced or made, that relates exclusively to any Transferred Asset or the Business, but

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<sup>1</sup> Note to Draft: Subject to diligence on whether there are any Commingled Contracts executed after the Option Agreement Effective Date or was not previously provided for diligence.

only to the extent based on actions or omissions by Prelude or any of its Affiliates prior to the Closing Date (and not resulting from any post-Closing acts or omissions by Incyte or its Affiliates);

- (f) any Liabilities resulting from, arising out of or relating to the employment or engagement (or termination of same) by Prelude or any of its Affiliates of any individual, including current and former employees or any benefit plan, in each case whether on, prior to or after the Closing Date;
- (g) any Liabilities resulting from, arising out of or relating to Intellectual Property Rights owned by or licensed to Prelude or any of its Affiliates which do not qualify as Transferred Assets, except any Liabilities resulting from the use of such Intellectual Property Rights by or on behalf of Incyte following the Closing;
- (h) any accounts payable relating to the Transferred Assets accrued as of or prior to the Closing Date (whether or not recorded on the books and records of Prelude prior to the Closing Date);
- (i) any indebtedness of Prelude or any of its Affiliates, whether or not related to the V617F Molecules; and
- (j) all Liabilities related to Taxes with respect to any of the Transferred Assets, the Business or any of the Assumed Liabilities, in respect of taxable periods, or portions thereof ending on or before the Closing.

“Executive Officers” means the Chief Executive Officer of Incyte (or a senior executive officer of Incyte designated by Incyte’s Chief Executive Officer) and the Chief Executive Officer of Prelude (or a senior executive officer of Prelude or its Affiliate as designated by Prelude’s Chief Executive Officer).

“FDA” means the United States Food and Drug Administration, or any successor agency thereto or authority in the United States having substantially the same function.

“First Commercial Sale” means, on a Product-by-Product and country-by-country basis, the first sale of such Product in such country by Incyte or its Affiliates or Licensees to any Third Party (other than a Licensee).

[\*\*\*]

“Fraud” means, with respect to a Party, actual and intentional common law fraud as defined under Delaware law on the part of such Person, as determined by a court of competent jurisdiction. For the avoidance of doubt, “Fraud” shall not include any claim based on constructive knowledge, recklessness, negligent misrepresentation or any similar theory, any extra-contractual statement, projection, estimate or forecast, or any omission, or any reliance other than on the express representations and warranties set forth in this Agreement.

“Generic Competition” means, with respect to a Product in any country, that [\*\*\*].

“Generic Product” means, on a Product-by-Product and country-by-country basis, a product that (a) contains the same or substantially the same V617F Molecule(s) as such Product, (b) is approved for use in such country by the applicable Regulatory Authority based in whole or in part on the data filed to support

Regulatory Approval of the Product, whether approved under an NDA, an ANDA, an application under Section 505(b)(2) of the FD&C Act, or any equivalent thereof, or otherwise by a Regulatory Authority and (c) is sold in the same country as such Product by any Third Party that is not Incyte, its Affiliates, or their sublicensees and that did not purchase such product in a chain of distribution that included Incyte or any of its Affiliates or their sublicensees.

“Governmental Authority” means any multinational, supra-national, federal, state, local, municipal or other governmental authority of any nature (including any Regulatory Authority and any governmental association, division, prefecture, subdivision, department, agency, bureau, branch, office, commission, committee, council, court or other tribunal, such as statutory health insurance funds and their associations), in each case having jurisdiction over the applicable subject matter.

[“HSR Act” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and any regulations promulgated thereunder.]

“IND” means an Investigational New Drug Application (as defined in the U.S. Federal Food, Drug and Cosmetics Act and the regulations promulgated thereunder (21 C.F.R. §312)), or, in the event that, at Incyte’s sole option, Incyte decides to submit any other investigational new drug application, clinical trial authorization, or similar application, submission, or a clinical trial exemption to the applicable Regulatory Authority of any country or jurisdiction outside of the U.S., such application, submission or exception, in each case, which must be approved, cleared or authorized by the applicable Regulatory Authority to commence or conduct any Trial of a pharmaceutical or biological product in humans in such jurisdiction, and all supplements and amendments to any of the foregoing.

“Indication” means with respect to a Product, a separate and distinct disease or medical condition that such Product is intended to treat, cure, mitigate, control, prevent, diagnose, monitor or ameliorate (*e.g.*, breast cancer and non-small cell lung cancer are distinct diseases).

“Intellectual Property Rights” means all intellectual property and industrial property rights of every kind and description throughout the world, including all (i) Patents, (ii) Know-How, (iii) trademarks, service marks, names, corporate names, trade names, logos, slogans, trade dress, design rights, internet domain names, social media designations and other similar designations of source or origin, together with the goodwill symbolized by any of the foregoing and applications and registrations for the foregoing, and (iv) copyrights and copyrightable subject matter, including any applications and registrations for the foregoing.

“Know-How” means any information, ideas, data, inventions, works of authorship, database rights, trade secrets, technology, practices, techniques, procedures, knowledge, skill, experience or materials, including formulations, molecules, assays, reagents, compounds, biologic molecules, compositions, human or animal tissue, samples or specimens, and combinations or components thereof, whether or not proprietary or patentable, or public or confidential, and whether stored or transmitted in oral, documentary, electronic or other form, including all regulatory documentation, but excluding any such information or materials publicly disclosed in Patents.

“Law” shall mean any federal, state, regional, county and local law, statute, ordinance, legally binding rule, directive or regulation, code, judgment, constitution, principle of common law, edict, treaty, ruling or directive or similar regulation of general applicability of (i) any government, governmental or quasi-governmental authority, entity, ministry, department, commission, board, agency or instrumentality, (ii) any court, tribunal, or judicial or arbitral body, whether federal, state, provincial, local or foreign and

(iii) any body exercising or entitled to exercise any administrative, executive, judicial, legislative, regulatory or tax authority or power of any nature.

“Liabilities” means any and all debts, liabilities, commitments and obligations of any kind, whether fixed, contingent or absolute, matured or unmatured, liquidated or unliquidated, accrued or not accrued, asserted or not asserted, known or unknown, determined, determinable or otherwise, whenever or however arising (including, whether arising out of any contract or tort based on negligence or strict liability).

“Licensee” means a Third Party to whom Incyte (or its Affiliate) has granted a license, sublicense or other rights, specifically excluding distributors and excluding contract manufacturing organizations with a right to Manufacture on behalf of a Party (or its Affiliate or its (sub)licensee) only.

“Losses” means any actual out-of-pocket damages, losses, payments, Liabilities, deficiencies, assessments, interest, penalties, fees, costs (including reasonable and documented out-of-pocket costs of investigation and defense), amounts paid in settlement and expenses (including reasonable and documented attorneys’ fees and expenses).

“Manufacturing” or “Manufacture” means all activities related to the manufacturing of any molecule or product, or a combination or comparator product, or any ingredient thereof, including manufacturing for clinical use or commercial sale, in-process and lot release testing, release, certification, filling, labelling and packaging, quality assurance activities related to such aforementioned manufacturing as well as handling and storage of any such molecule, product or ingredient.

“Material Adverse Effect” means any Change that, individually or taken together with any other Changes is, or would reasonably be expected to be, materially adverse to the condition (financial or otherwise), assets, Liabilities (contingent or otherwise), business operations or results of operations of the Business, taken as a whole; provided, however, that none of the following, either alone or in combination, shall be deemed to constitute or be taken into account in determining whether a Material Adverse Effect is occurring, has occurred or would reasonably be expected to occur:

- (a) Changes in or with respect to the economy, credit, capital, securities or financial markets or political, regulatory or business conditions in the U.S.;
- (b) Changes that are the result of factors generally affecting the biopharmaceutical industry;
- (c) Changes in applicable accounting standards, including GAAP, or in any Law of general applicability or the interpretation or enforcement thereof, in each case, after the Execution Date;
- (d) any Change resulting from acts of war (whether or not declared), sabotage, terrorism, military actions or the escalation of any of the foregoing, whether perpetrated or encouraged by a state or non-state actor or actors (other than cyberattacks), any weather or natural disaster, whether or not caused by any Person (other than Prelude or any of its Affiliates or Representatives);
- (e) any actions taken by Prelude at Incyte’s written request after the Execution Date;
- (f) earthquakes, hurricanes, pandemics (including COVID-19), epidemics, natural disasters or any other force majeure event, whether or not caused by any Person or any national or international calamity or crisis;

- (g) failure to meet projections, estimates, plans or forecasts;
- (h) Changes that arise out of or are attributable to the negotiation, execution, announcement or pendency of the transactions contemplated hereby (including the fact that the prospective owner of the Transferred Assets is Incyte);
- (i) any labor strikes, labor stoppages or loss of employees; and
- (j) currency or interest rate fluctuations;

provided, further, that, with respect to clauses (a), (b), (c) and (d) of this definition, such Changes shall be taken into account in determining whether a "Material Adverse Effect" is occurring or has occurred or would reasonably be expected to occur to the extent it disproportionately and adversely affects the Business relative to other businesses operating in the geographic markets or industries in which the Business operates.

"Net Sales" means, with respect to any Product, gross amount invoiced by Incyte or its Affiliates, and its and their Licensees, of such Product sold to Third Parties (including a customer, distributor, wholesaler or end user) (the "Sold Product") less the following deductions from such gross amounts which are actually incurred, allowed, paid, accrued or specifically allocated to the extent that such amounts are deducted from gross invoiced sales amounts as calculated in accordance with GAAP, applied on a consistent basis:

- (a) [\*\*\*].

In the case of any sale or other disposal of the Sold Product between or among Incyte and its Affiliates, and Licensees for resale, Net Sales shall be deemed to occur and shall be calculated as above only after the First Commercial Sale of such Product.

In the case of any sale that is not invoiced or is delivered before invoice, Net Sales shall be calculated at the time all the revenue recognition criteria under the applicable Accounting Standards are met.

In the case of any sale or other disposal for value, such as barter or counter-trade, of Product, or part thereof, other than in an arm's length transaction exclusively for cash, Net Sales shall be calculated as above on the value of the non-cash consideration received or the fair market price (if higher) of the Product in the country of sale or disposal, as determined in accordance with Incyte's applicable accounting standards.

In the event the Product is sold in a finished dosage form containing the Product in combination with one or more other active ingredients (a "Combination Product"), the Net Sales of the Product, for the purposes of determining royalty payments, shall be determined:

(a) if the Product and other active ingredients contained in the Combination Product are each sold separately in finished form, by multiplying the Net Sales (as defined above) of the Combination Product by the fraction, [\*\*\*];

(b) if the Product contained in the Combination Product is sold separately in finished form but the other active ingredients are not sold separately in finished form, by multiplying the Net Sales (as defined above) of the Combination Product by the fraction, [\*\*\*]; and

(c) [\*\*\*].

“Net Sales Payment Bearing Patent” means any [\*\*\*].

“Non-Fundamental Representation” means any representation or warranty set forth in Section 3.1, other than the representations and warranties set forth in Section 3.1(a), Section 3.1(b) and Section 3.1(i).

“Order” means any administrative decision or award, decree, injunction, judgment, order, quasi-judicial decision or award, ruling or writ, whether temporary, preliminary or permanent, of any arbitrator, mediator or Governmental Authority.

“Outside Date” means [●].<sup>2</sup>

“Patent” means all patents and patent applications in any country in the world, including any continuations, continuations-in-part, divisionals, non-provisionals, provisionals, any international application under the Patent Cooperation Treaty, regional application, or any substitute applications, any patent issued with respect to any such patent applications, any reissue, reexamination, renewal or extension (including any Patent Term Extension or supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all counterparts or equivalents of any of the foregoing anywhere in the world.

“Patent Assignment Agreement” means the Patent Assignment Agreement between Prelude, on the one hand, and Incyte, on the other hand, in substantially the form attached hereto as Exhibit B.<sup>3</sup>

“Patent Term Extension” means any patent term extension, adjustment or restoration or supplementary protection certificate anywhere in the world.

“Permitted Encumbrance” means (i) any Encumbrance for Taxes that are not due and payable, and (ii) in the case of any contract, Encumbrances that are restrictions against the transfer or assignment thereof that are included in the terms of such contract.

“Person” means any natural person and any corporation, company, partnership (general or limited), unincorporated association (whether or not having separate legal personality), trust, Governmental Authority or other entity.

“Phase I Study” means a study in humans which provides for the first introduction into humans of a product, conducted in healthy volunteers or patients to obtain information on product safety, tolerability, pharmacological activity or pharmacokinetics, as more fully defined in 21 C.F.R. § 312.21(a) (as amended or any replacement thereof or the non-United States equivalent thereof).

“Phase Ib/II Study” means a clinical study of a pharmaceutical product in human subjects that (a) follows completion of a monotherapy dose escalation portion of a Phase I Study and (b) is designed to (i) further evaluate safety, tolerability, pharmacokinetics, and pharmacodynamics of one or more dose levels and/or regimens of such product, as more fully defined in 21 C.F.R. Section 312.21(a) (as amended or any

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<sup>2</sup> Note to Draft: To be the date that is three months following the Execution Date of this Agreement.

<sup>3</sup> Note to Draft: If there are any other registered Intellectual Property Rights, Parties will enter into a similar assignment agreement.

replacement thereof or the non-United States equivalent thereof) and (ii) obtain preliminary evidence of efficacy in patients with the target indication.

“Post-Option Exercise Patent” has the meaning set forth in the Option Agreement.

“Post-Option Exercise V617F Program Activities” has the meaning set forth in the Option Agreement.

“Price Reduction Subject Product” means a product that has been designated as a “selected drug” and made subject to a “maximum fair price” pursuant to the Inflation Reduction Act or any other price control, negotiation or reduction mechanism imposed by a Governmental Authority, including “most favored nation” pricing requirements, executive orders or regulations mandating price parity with foreign markets, mandatory rebates, discounts or pricing caps imposed by a Governmental Authority, or any successor legislation or policy initiative that imposes government-mandated pricing constraints on such product, whether implemented through statute, regulation, executive action or administrative policy.

“Pricing Approval” means the approval, agreement, determination or decision from a Governmental Authority or a private payer establishing the final net price and reimbursement for a Product for sale in a given country or regulatory jurisdiction, in such country or other regulatory jurisdiction prior to or subsequent to the marketing and sale of a Product in such country or regulatory jurisdiction.

“Product” means any product, whether alone or together with other active ingredients, in any dosage strength, form or formulation and for any mode of administration, that contains one or more of [\*\*\*].

“Registrational Trial” means, with respect to a Product, either: (a) a Trial of such Product in humans that meets the requirements of 21 C.F.R. § 312.21(c), as amended (or its successor regulation), or (b) any other Trial of a Product on a sufficient number of subjects that: (A) is designed to establish that such Product has an acceptable safety and efficacy profile for its intended use, and to determine warnings, precautions and adverse reactions that are associated with such Product in the dosage range to be prescribed, which trial is intended to support filing of a Drug Approval Application of such Product, or a similar clinical study prescribed by the applicable Regulatory Authority; and (B) is a registration trial that would be sufficient for filing of a Drug Approval Application for such Product, as evidenced by: (x) a written agreement with or written statement from the applicable Regulatory Authority on a special protocol assessment or its equivalent, or (y) other written minutes or other Regulatory Materials issued by the applicable Regulatory Authority for such registration trial.

“Regulatory Activities” means activities by or on behalf of the Parties or their Affiliates (or their (sub)licensee(s) or subcontractor(s)) with respect to (a) preparation, filing, obtaining and maintaining Regulatory Approvals, (b) preparation of Regulatory Materials and (c) calls and meetings with Regulatory Authorities, all with respect to the V617F Molecules.

“Regulatory Approvals” means all approvals, licenses, registrations, and authorizations of any federal, national, multinational, state, provincial or local Regulatory Authority, department, bureau and other Governmental Authority that are necessary for the marketing and sale of a product in a country or group of countries, except for Pricing Approvals.

“Regulatory Authority” means, with respect to a country, the regulatory authority or regulatory authorities of such country (including state and local) with authority over the testing, Manufacture, use,

storage, disposal, importation, promotion, marketing, pricing or sale of a pharmaceutical or biologic product in such country.

“Regulatory Data” means any and all research data, pharmacology data, chemistry, manufacturing and control data, preclinical data, clinical data and all other documentation submitted, or required to be submitted, to Regulatory Authorities in association with obtaining or maintaining all Regulatory Approvals and Pricing Approval for the Product in the entire world (including relevant parts of any applicable Drug Master Files, Chemistry, Manufacturing and Control data, Common Technical Document or similar documentation).

“Regulatory Materials” means regulatory applications, submissions, notifications, communications, correspondence, registrations or other filings submitted to, made to, received from or otherwise conducted with a Regulatory Authority that are necessary in order to Develop, Manufacture, obtain and maintain Regulatory Approvals, market, sell or otherwise Commercialize the Product in a particular country or regulatory jurisdiction. Regulatory Materials include materials relating to pre-IND meetings, INDs, pre-Marketing Authorization Application, Marketing Authorization Applications, presentations, responses, and applications for other Regulatory Approvals.

“Related Patents” means, with respect to a specified Patent, all Patents in any country of the world claiming priority to, sharing priority with, or from which priority is claimed by, such specified Patent, together with any and all U.S. and foreign counterparts thereof.

“Related to the Business” means exclusively related to, or used **exclusively** in connection with, the Business as conducted by Prelude and its Affiliates immediately prior to the Closing.

“Representative” of a Person means any Affiliate, officer, director, manager, employee, stockholder, member or equityholder of such Person or any investment banker, attorney, accountant or other advisor, agent or representative of such Person.

[\*\*\*].

“Subsidiary” means, with respect to any Person, any other Person of which at least a majority of the securities or ownership interests having by their terms ordinary voting power to elect a majority of the board of directors or other Persons performing similar functions is directly or indirectly owned or controlled by such Person or by one or more of its Subsidiaries.

“Tax” means any tax (including any net income tax, gross income tax, franchise tax, capital gains tax, gross receipts tax, gross profits tax, branch profits tax, windfall profits tax, capital tax, value-added tax, surtax, estimated tax, employment tax, unemployment tax, national health insurance tax, severance tax, social security tax or other similar contribution, disability tax or other similar contribution, occupancy tax, excise tax, estimated tax, alternative or minimum tax, ad valorem tax, transfer tax, stamp tax, documentary tax, premium tax, sales tax, use tax, service tax, property tax, business tax, capital stock tax, withholding tax, backup tax or payroll tax), levy, assessment, tariff, impost, imposition, duty (including any customs duty), or other tax or charge of any kind whatsoever, imposed, assessed or collected by or under the authority of any Governmental Authority, together with any interest, penalties, inflationary adjustments, additions to tax, fines or other additional amounts imposed thereon, with respect thereto, or related thereto.

“Tax Return” means any return (including any information return), report, statement, declaration, estimate, schedule, form, election, certificate, application for refund or other document or information filed

or required to be filed with any Governmental Authority in connection with the determination, assessment, collection or payment of any Tax and any attachments thereto or amendments thereof.

“Third Party” means any Person other than a Party or an Affiliate of a Party.

“Transaction Documents” means this Agreement, the Assignment and Assumption and Bill of Sale Agreement, the Patent Assignment Agreement and the other agreements, instruments and documents required to be delivered at the Closing.

“Transferred Assets” has the meaning set forth in Section 2.1.

“Trial” means any clinical study or clinical trial (including interventional clinical trials) in which a Product is administered or otherwise evaluated in humans or any non-interventional, retrospective or observational studies related to any Product.

“U.S. Approval” means, with respect to a Product, the approval of a Drug Approval Application for such Product by the FDA, including any Accelerated Approval.

“V617F Molecules” means all V617F Mutative Selective Inhibitors that are owned and controlled by Prelude or its Subsidiaries as of the Execution Date [\*\*\*].

“V617F Mutative Selective Inhibitors” means any molecules that bind the JAK2 pseudokinase domain (JH2) [\*\*\*].

“Valid Claim” means, with respect to a particular country, a claim of (a) a Patent that is issued and unexpired and has not been (i) held permanently revoked, unenforceable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, from which decision is unappealable or unappealed within the time allowed for appeal, or (ii) cancelled, withdrawn, abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (b) a pending patent application that has not been abandoned or finally rejected without the possibility of appeal or refiling and that has not been pending for more than [\*\*\*].

#### **Other Definitions**

AAA  
Acquisition  
Agreement  
Assumed Liabilities  
Audit Team  
Closing  
Closing Date  
Commingled Contract  
Company Schedules  
Competing Project  
Contingent Payments  
Development Data  
Dispute  
Effective Time  
Evaluation Material  
Exclusivity Period  
Execution Date

#### **Section References**

Section 8.8(b)  
Section 2.7(c)  
Preamble  
Section 2.2  
Section 2.6(f)(ii)  
Section 2.4  
Section 2.4  
Section 4.8  
Section 3.1  
Section 2.7(b)  
Section 2.6(b)(i)  
Section 2.1(e)  
Section 8.8(a)  
Section 2.4  
Section 3.1(l)  
Section 2.7(a)  
Preamble

**Other Definitions**

[\*\*\*] Milestone  
[\*\*\*] Registrational Trial Milestone  
[\*\*\*] Trial  
[\*\*\*] U.S. Approval Milestone  
Incyte  
Incyte Indemnified Party  
Indemnified Party  
Indemnifying Party  
Knowledge of Prelude  
Milestone  
Milestone Deduction Cap  
Milestone Payment  
Net Sales Payment  
Net Sales Statement  
Net Sales Term  
New Contract  
Nonassigned Asset  
Option Agreement  
Parties  
Party  
Payee  
Payer  
Prelude  
Prelude Blocking Patent  
Prelude Indemnified Party  
Price Reduction Quarter  
Product Transfer  
Records  
Registrational Trial Milestone  
Relevant Part  
Rules  
[\*\*\*]  
[\*\*\*]  
Segregate  
Third Party Claim  
Third Party Transferee  
Transfer Taxes  
Transferred Assets  
Transferred Contracts  
Transferred Know-How  
Transferred Patents  
Transition Period  
U.S. Approval Milestone

**Section References**

Section 2.6(a)(i)  
Section 2.6(a)(iii)  
Section 2.6(e)(ii)  
Section 2.6(a)(v)  
Preamble  
Section 7.2  
Section 7.5(a)  
Section 7.5(a)  
Section 3.1(f)  
Section 2.6(a)  
Section 2.6(c)(i)  
Section 2.6(a)  
Section 2.6(b)(i)  
Section 2.6(b)(ii)  
Section 2.6(b)(i)  
Section 4.8  
Section 4.7  
Recitals  
Preamble  
Preamble  
Section 4.9(a)  
Section 4.9(a)  
Preamble  
Section 4.10  
Section 7.3  
Section 2.6(c)(iii)  
Section 2.6(i)  
Section 4.6  
Section 2.6(a)(iii)  
Section 4.8  
Section 8.8(b)  
Section 2.6(a)(iv)  
Section 2.6(a)(iii)  
Section 2.7(b)  
Section 7.5(b)  
Section 2.6(i)  
Section 4.9(b)  
Section 2.1  
Section 2.1(a)  
Section 2.1(b)  
Section 2.1(c)  
Section 2.6(e)(iii)  
Section 2.6(a)(iv)

**Section 1.2 Interpretation; Construction.**

(a) Where a reference in this Agreement is made to an Annex, Exhibit, Section or Schedule, such reference shall be to an Annex, Exhibit, Section or Schedule to this Agreement unless otherwise

indicated. The headings in this Agreement are for reference only and shall not affect the interpretation of this Agreement.

(b) If a term is defined as one part of speech (such as a noun), it shall have a corresponding meaning when used as another part of speech (such as a verb). The terms defined in the singular have a comparable meaning when used in the plural and vice versa. Unless the context of this Agreement clearly requires otherwise, words importing the masculine gender shall include the feminine and neutral genders and vice versa. Whenever the words “include,” “includes” or “including” are used in this Agreement, they shall be deemed to be followed by the words “without limitation.” The words “hereof,” “herein” and “hereunder” and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The word “or” shall not be exclusive. Currency amounts referenced herein are in U.S. Dollars. Any capitalized term used in any Schedule or Exhibit but not otherwise defined therein shall have the meaning given to them as set forth in this Agreement. All accounting terms used herein and not expressly defined herein shall have the meanings given to them under GAAP. References to “written” or “in writing” include documents in electronic form or transmission by email. A reference to any Person includes such Person’s successors and permitted assigns.

(c) Except as otherwise specifically provided herein, all references in this Agreement to any Laws include the rules and regulations promulgated thereunder, in each case as amended, re-enacted, consolidated or replaced from time to time and in the case of any such amendment, re-enactment, consolidation or replacement, reference herein to a particular provision shall be read as referring to such amended, re-enacted, consolidated or replaced provision and shall also include, unless the context otherwise requires, all applicable guidelines, bulletins or policies made in connection therewith.

(d) Any contract, agreement or instrument referred to herein means such contract, agreement or instrument as from time to time amended, modified or supplemented, including by waiver or consent and all attachments thereto and instruments incorporated therein.

(e) Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified. Whenever any action must be taken hereunder on or by a day that is not a Business Day, then such action may be validly taken on or by the next day that is a Business Day.

(f) The Parties have drafted this Agreement jointly through the exchange of drafts hereof, so no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provision of this Agreement.

## **ARTICLE II PURCHASE AND SALE; CLOSING; DELIVERIES**

Section 2.1 Purchase and Sale of the Assets. Upon the terms and subject to the conditions set forth in this Agreement, Prelude shall, and shall cause its Affiliates to, sell, assign, transfer, convey and deliver to Incyte, and Incyte shall purchase, acquire and accept from Prelude, Prelude’s and its Affiliates’ entire right, title and interest in and to the following assets, properties and rights of Prelude and its Affiliates that are Related to the Business (in each case to the extent that such assets, properties and rights exist as of

the Closing Date), excluding the Excluded Assets (collectively, the “Transferred Assets”), free and clear of any and all Encumbrances, other than Permitted Encumbrances:

(a) all contracts and agreements with Third Parties that are in effect, and to which Prelude or any of its Affiliates is a party, as of the Closing Date that are Related to the Business, including those set forth in Section 2.1(a) of the Company Schedules (collectively, the “Transferred Contracts”);

(b) all right, title and interest in and to Know-How Related to the Business, including those set forth in Section 2.1(b) of the Company Schedules, together with the assay and related Know-How described in Exhibit C (collectively, the “Transferred Know-How”), and including all rights to sue for past, present, or future infringement or other violation, and to retain any damages and profits due or accrued for any such past, present or future infringement or other violation of such Transferred Know-How;

(c) all right, title and interest in and to the Patents that are Related to the Business, including those set forth in Section 2.1(c) of the Company Schedules and all Related Patents (collectively, the “Transferred Patents”), including all rights of priority and renewals, all rights to sue for past, present, or future infringement or other violation, and to retain any damages and profits due or accrued for any such past, present or future infringement or other violation of such Transferred Patents;

(d) all prosecution history files, inventor notes, assignments, lab notebooks, discovery notes and other documents and files that are Related to the Business or otherwise pertaining to the Transferred Patents or Transferred Know-How and in Prelude’s or its Affiliates’ possession, ownership or control;

(e) to the extent permitted by Law, all development data (including all raw clinical data, SAS datasets, Trial master files, Regulatory Data and regulatory correspondence and minutes of meetings with Governmental Authorities), to the extent Related to the Business and in Prelude’s or its Affiliates’ possession or control (“Development Data”);

(f) to the extent permitted by Law, any correspondence with the FDA, EMA or other Governmental Authority in Prelude or any of its Affiliates’ possession or control to the extent Related to the Business;

(g) all clinical inventory and clinical samples in Prelude’s or Affiliates’ control used in or derived from a Trial (including all patient tissue, blood samples and relevant analyses) conducted by Prelude or its Affiliate to the extent Related to the Business; and

(h) all Actions available to or being pursued by Prelude or any of its Affiliates to the extent Related to the Business or the ownership, use, function or value of any Transferred Asset.

Section 2.2 Assumed Liabilities; Excluded Liabilities. Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, Incyte shall assume, satisfy, perform, pay, discharge and otherwise be responsible for any and all Liabilities obligations, commitments and undertakings of Prelude and its Affiliates of any nature, whether known or unknown, accrued or unaccrued, absolute or contingent, due or to become due, and whether arising, existing or asserted before or after the Closing, to the extent pertaining to, arising from or related to the Transferred Assets or Business solely to the extent arising out of or relating to Incyte’s ownership or operation of the Transferred Assets or the Business on or after the Closing (including any such Liabilities arising out of or relating to the research, Development, Manufacture, Commercialization or other exploitation of any Product by or on behalf of Incyte (or any of its Affiliates)) and, in the case of Transferred Assets that are Transferred Contracts, to the extent such Liabilities do not exclusively relate to any failure to perform, improper performance, warranty or other

breach, default or violation by Prelude or any of its Affiliates on or prior to the Closing (the “Assumed Liabilities”). Except to the extent (a) expressly included in the Assumed Liabilities or (b) to be paid, assumed or otherwise borne by Incyte in accordance with the terms of this Agreement, Incyte will not assume or be responsible or liable for any Excluded Liabilities. Prelude, without any further responsibility or liability of, or recourse to, Incyte, or any of Incyte’s directors, shareholders, officers, employees, agents, consultants, Representatives, Affiliates, successors or assigns, absolutely and irrevocably assumes and agrees to be solely liable and responsible for the Excluded Liabilities.

Section 2.3 Consideration. In consideration of the sale, conveyance, delivery, transfer and assignment of the Transferred Assets to Incyte and Incyte’s assumption of Assumed Liabilities and Prelude’s other covenants and obligations hereunder, at the Closing, upon the terms and subject to the conditions hereof, Incyte shall pay, or cause to be paid, to Prelude, in cash by wire transfer of immediately available funds to the account or accounts specified by Prelude to Incyte at least one Business Day prior to the anticipated Closing Date, the Closing Cash Consideration.

Section 2.4 Time and Place of Closing. The closing of the purchase and sale of the Transferred Assets and assumption of the Assumed Liabilities under this Agreement (the “Closing”) shall take place by remote communications and by the exchange of signatures by electronic transmission (including DocuSign) [on the third Business Day following the satisfaction or, to the extent permitted by applicable Law, waiver of the last condition in Article V to be satisfied or waived (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the fulfillment or, to the extent permitted by applicable Law, waiver of those conditions)][on the date hereof]<sup>4</sup>, or at such other place (or by means of remote communication) and date as the Parties may agree in writing (the actual date of the Closing, the “Closing Date”). The Closing will be effective as of 12:01 a.m., New York City time, on the Closing Date (the “Effective Time”).

Section 2.5 Deliveries at Closing.

(a) By Prelude. Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, Prelude shall deliver or cause to be delivered to Incyte:

- (i) counterparts of each Transaction Document to which Prelude is a party, in each case, duly executed by Prelude;
- (ii) a duly executed I.R.S. Form W-9; and
- (iii) the certificate contemplated by Section 5.2(c).

(b) By Incyte. Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, Incyte shall deliver or cause to be delivered to Prelude:

- (i) the Closing Cash Consideration by wire transfer of immediately available funds;
- (ii) counterparts of each Transaction Document to which Incyte is a party, in each case, duly executed by Incyte; and

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<sup>4</sup> Note to Draft: To be updated prior to the execution of this Agreement based on Incyte’s determination of whether an HSR filing is necessary pursuant to Section 5.1(c) of the Option Agreement.

(iii) the certificate contemplated by Section 5.3(c).

Section 2.6 Contingent Consideration; Diligence.

(a) Milestone Payments. As additional consideration for the transactions contemplated hereby, solely upon the achievement of the corresponding milestone event set forth in each subsection of this Section 2.6(a) (each of the [\*\*\*] Milestone, the two Registrational Trial Milestones and the two U.S. Approval Milestones, a “Milestone”), Incyte shall, subject to the terms of this Section 2.6, pay or cause to be paid to Prelude in cash the amount specified below (each such payment, a “Milestone Payment”), which Milestone Payment shall be non-creditable and non-refundable:

(i) upon the first dosing of the [\*\*\*] patient [\*\*\*] within an Indication in a Phase Ib/II Study [\*\*\*] any Product that contains [\*\*\*], \$100,000,000 [\*\*\*];

(ii) upon the first dosing of the [\*\*\*] subject in the first Registrational Trial in the U.S. of any Product that contains [\*\*\*] contain [\*\*\*], \$75,000,000 [\*\*\*];

(iii) upon the first dosing of the [\*\*\*] subject in the first Registrational Trial in the U.S. of any Product that contains [\*\*\*], \$100,000,000 [\*\*\*];

(iv) upon the first U.S. Approval for any Product that contains [\*\*\*], \$175,000,000 [\*\*\*];

(v) upon the first U.S. Approval for any Product that contains [\*\*\*], \$325,000,000 [\*\*\*].

Incyte shall promptly deliver, or cause to be delivered, written notice to Prelude of the achievement of any Milestone (but in any event no later than five Business Days after the occurrence thereof), and, within 30 days of the delivery of such notice, Incyte shall deliver, or cause to be delivered, the applicable Milestone Payment to Prelude by wire transfer of immediately available funds to such bank account as may be designated in writing by Prelude. For clarity, in no event shall any Milestone Payment be made more than once and in no event shall any Milestone Payment be made for more than one Product; provided that, for the avoidance of doubt, in no event shall Incyte pay more than \$175,000,000 in the aggregate for achievement of the Registrational Trial Milestones or more than \$500,000,000 in the aggregate for achievement of the U.S. Approval Milestones. For the avoidance of doubt, [\*\*\*].

If [\*\*\*] subsequently achieves the Registrational Trial Milestone, then [\*\*\*] shall be deemed achieved and Incyte shall, subject to the terms of this Section 2.6, pay or cause to be paid to Prelude the Milestone Payment corresponding to [\*\*\*].

If [\*\*\*] subsequently receives U.S. Approval, then [\*\*\*] shall be deemed achieved and Incyte shall, subject to the terms of this Section 2.6, pay or cause to be paid to Prelude the Milestone Payment corresponding to [\*\*\*].

If [\*\*\*] subsequently receives U.S. Approval, then [\*\*\*] shall be deemed achieved and Incyte shall, subject to the terms of this Section 2.6, pay or cause to be paid to Prelude the Milestone Payment corresponding to [\*\*\*].

(b) Net Sales Payments.

(i) As additional consideration for the transactions contemplated hereby, on a Product-by-Product and country-by-country basis, with respect to the Net Sales of a particular Product in a country until the latest of: (a) [\*\*\*] years after the First Commercial Sale of such Product in such country, (b) the expiration of the last to expire of [\*\*\*] and (c) the expiration [\*\*\*] (the “Net Sales Term”), Incyte shall, subject to the terms of this Section 2.6, pay or cause to be paid to Prelude, for each calendar quarter during the Net Sales Term, (x) for any Product that contains [\*\*\*], an amount in cash equal to [\*\*\*] percent of Net Sales of such Product in such country based on the Net Sales of such Product in such country in such calendar quarter and (y) for any Product that contains [\*\*\*], an amount in cash equal to [\*\*\*] percent of Net Sales of such Product in such country based on the Net Sales of such Product in such country in such calendar quarter (each such payment in clause (x) or (y), a “Net Sales Payment” and collectively with the Milestone Payments, the “Contingent Payments”). For the avoidance of doubt, (A) with respect to any Product, in no event shall any Net Sales Payment be made more than once, and in no event shall more than one royalty rate apply to the same Product, and (B) if a Product contains [\*\*\*], such Product shall be only subject to a single royalty rate of [\*\*\*] percent of Net Sales.

(ii) Within 45 days following the end of each calendar quarter, Incyte shall prepare and deliver to Prelude a written report with respect to such calendar quarter with sufficient detail to permit the confirmation of the accuracy of any Net Sales Payments made in such calendar quarter, including, on a Product-by-Product and country-by-country basis: (A) the amount of gross sales and Net Sales (in U.S. Dollars); (B) the number and category of Products; (C) the Net Sales Payment (in U.S. Dollars); and (D) the exchange rate used to calculate the Net Sales Payment (a “Net Sales Statement”). The Parties acknowledge and agree that each Net Sales Statement, and the component items and calculations therein, shall be prepared in a manner consistent with the terms of this Agreement. Incyte shall pay, or cause to be paid, to Prelude all Net Sales Payments due under this Agreement with respect to a calendar quarter within 45 days after the end of each calendar quarter.

(c) Contingent Payment Adjustments. The following adjustments will be made, on a Product-by-Product and country-by-country basis, to the Contingent Payments:

(i) Third Party Rights. If Incyte [\*\*\*] to obtain a license under any Patents of a Third Party that would be infringed by the making, having made, using, selling, offering for sale or importing by Incyte of a Product in a given country, then Incyte shall have the right to obtain a license by negotiating and executing a license agreement with such Third Party to Manufacture, Develop or Commercialize such Product in such country. If Incyte seeks and obtains a license after the Closing [\*\*\*] and Incyte [\*\*\*] under the license agreement in any calendar quarter from and after the Closing with such Third Party in order to obtain such license, then Incyte will have the right to deduct [\*\*\*] actually paid by Incyte under such license agreement with such Third Party in such calendar quarter that result from the sale such Product (or any Development Candidate contained therein, but not any other component therein) by or on behalf of Incyte in such country, in each case to the extent reasonably apportioned to such Product; provided that in no event will any such Net Sales Payments be reduced on account of such deduction by more than [\*\*\*]% of the Net Sales Payment otherwise due with respect to such Product and country in such calendar quarter.

(ii) Generic Entry. Further, in the event that Generic Competition exists with respect to a given Product in a given country, the Net Sales Payments owed with respect to such Product in such country will be reduced by [\*\*\*]% beginning from [\*\*\*] and for so long as [\*\*\*].

(iii) Price Reduction Subject Products. Further, in the event that a Product becomes a Price Reduction Subject Product in a country, beginning from the calendar quarter immediately after (i) the date on which the price of the Product in such country first becomes reduced with or without drug price negotiation as a result of such Product becoming a Price Reduction Subject Product in such country, or (ii) if, as applicable, drug price negotiation fails to reach agreement or no drug price negotiation occurs, the date on which an excise tax is levied on the sale of such Product (the calendar quarter during which such price reduction first occurred or such excise tax first levied, as applicable, the “Price Reduction Quarter”), the Net Sales Payments owed in such country for such Product will be reduced to [\*\*\*]. Notwithstanding the foregoing, in the event that, following a policy change of a Governmental Authority in such country, the average quarterly Net Sales of such Product in such country during [\*\*\*], then, effective as of [\*\*\*], such Product shall no longer be deemed a Price Reduction Subject Product, and the royalty reductions set forth in this Section shall cease to apply. For the avoidance of doubt, this does not preclude the same Product from being reclassified as a Price Reduction Subject Product at a later time, should the conditions set forth in this Section be met again.

(iv) Valid Claim Stepdown. For any portion of a given calendar quarter that such Product is not Covered by a Valid Claim of a Net Sales Payment Bearing Patent in such country, any Net Sales Payments owed with respect to such Product in such country solely in such portion of such calendar quarter shall be reduced by [\*\*\*]% for as long as no such Valid Claim exists.

(v) Cumulative Reduction Floor. In no event (without prejudice to the remedies and limitations contained in Article VII) will the aggregate Net Sales Payments due to Prelude with respect to any calendar quarter during the Net Sales Term for a given Product in a given country be reduced under this Section 2.6 by more than [\*\*\*]% of the amount that otherwise would have been due and payable to Prelude with respect to such calendar quarter for such Product under Section 2.6. Credits for reductions to Net Sales Payments pursuant to Section 2.6(c)(i) not exhausted in any calendar quarter as a result of the foregoing restriction in this Section 2.6(c)(v) may be carried into future calendar quarters and applied in accordance with Section 2.6(c)(i) with respect to such Product in such country until the earlier of (A) such excess amounts having been deducted in full or (B) the end of the applicable Net Sales Term, but subject in all cases to this Section 2.6(c)(v).

(d) Transferability. The right of Prelude to receive the Contingent Payments (i) is solely a contractual right and will not be evidenced by a certificate or other instrument, (ii) does not represent any equity or ownership interest in Incyte or any of its Affiliates and (iii) may not be sold, assigned, transferred, distributed, pledged, encumbered or in any other manner transferred or disposed of, in whole or in part, except (A) to any Affiliate, (B) by operation of Law or to any successor in interest to all or substantially all of Prelude’s business or assets (including by merger, consolidation, reorganization, sale of equity or assets, or by operation of law), (C) to any financing source or collateral agent as collateral security (with customary enforcement rights), or (D) with Incyte’s prior written consent not to be unreasonably withheld, conditioned or delayed.

(e) Information Transfer; Program Handoff.

(i) As promptly as practicable but within thirty (30) days after the Closing Date, the Parties shall in good faith agree upon a transition plan. From the Closing Date, subject to the continued conduct of any Post-Option Exercise V617F Program Activities pursuant to the Option Agreement, Prelude shall, at Incyte’s cost, effect a transition to Incyte of any Transferred Know-How with respect to V617F Molecules pursuant to the transition plan and cooperate with Incyte in

such transition and provide any technical assistance to effectuate such transfer as reasonably and appropriately requested by Incyte.

(ii) The Parties acknowledge that prior to the Closing Date, Prelude may have, at its sole discretion, conducted additional Development with respect to [\*\*\*]. Incyte shall reimburse Prelude for the reasonable and appropriately documented out-of-pocket costs incurred by Prelude in connection with such trial closeout, transfer and handoff activities. In furtherance of the transition plan, the Parties may be required to execute quality agreements and other documentation with applicable contract development and manufacturing organizations to effect the transfer of the clinical supply [\*\*\*].

(iii) As of the Closing Date, and solely for the term of the transition contemplated in this Section 2.6(e) (the “Transition Period”), Incyte hereby grants to Prelude and its Affiliates a non-exclusive, non-sublicensable, non-transferable limited license under any Intellectual Property Right that is a Transferred Asset to conduct the transition as set forth in this Section 2.6(e). The foregoing license shall automatically terminate at the end of the Transition Period.

(f) Audits.

(i) Incyte shall keep complete, true and accurate books of account and records which relate to the V617F Molecules and Products (including complete and accurate records of Net Sales, setting forth the gross invoiced amounts from sales of the Products and amounts deducted by category from gross invoiced amounts in reasonable detail) and all other data necessary for the purpose of determining the amounts payable under this Section 2.6.

(ii) Prelude may, upon request and at its expense (except as provided for herein), cause one of the “Big Four” accounting firms (Deloitte, Ernst & Young, KPMG or PricewaterhouseCoopers) selected by it (except one to whom Incyte has a reasonable objection based on the independence of the accounting firm) (the “Audit Team”) to audit during ordinary business hours the books and records of Incyte and the correctness of any payment made or required to be made to Prelude, and any report underlying such payment (or lack thereof), pursuant to the terms of this Agreement, including with respect to the Net Sales Statements set forth in Section 2.6(b). Prior to commencing its work pursuant to this agreement, the Audit Team shall enter into an appropriate confidentiality agreement with Incyte.

(iii) In respect of each audit of the Incyte’s books and records: (i) Incyte may be audited only once per year, (ii) no records for any given year for Incyte may be audited more than once; provided that Incyte’s records shall still be made available if such records impact another financial year which is being audited and (iii) Prelude shall only be entitled to audit books and records of Incyte from the three calendar years prior to the calendar year in which the audit request is made.

(iv) In order to initiate an audit for a particular calendar year, Prelude shall provide written notice to Incyte of one or more proposed dates of the audit not less than 60 days prior to the first proposed date. Incyte will reasonably accommodate the scheduling of such audit. Incyte shall provide such Audit Team(s) with full and complete access to the applicable books and records and otherwise reasonably cooperate with such audit.

(v) The audit report and basis for any determination by an Audit Team shall be made available first for review and comment by Incyte, and Incyte shall have the right, at its expense, to request a further determination by such Audit Team as to matters which Incyte disputes (to be

completed no more than 30 days after the first determination is provided to Incyte and to be limited to the disputed matters). If the Parties disagree as to such further determination, Prelude and Incyte shall mutually select one of the “Big Four” accounting firms (Deloitte, Ernst & Young, KPMG or PricewaterhouseCoopers) that shall make a final determination as to the remaining matters in dispute that shall be binding upon the Parties. Such accountants shall not disclose to Prelude any information relating to the business of Incyte except that which should properly have been contained in any report required hereunder or otherwise required to be disclosed to such Party to the extent necessary to verify the payments required to be made pursuant to the terms of this Agreement.

(vi) If an audit shows any under-reporting, underpayment or overpayment by Incyte, that under-reporting, underpayment or overpayment shall be reported to Prelude, and Incyte shall remit such underpayment to Prelude within 45 days after receiving the audit report, and any overpayment shall be credited against Incyte’s next payment(s) due under this Agreement. Further, if the audit for an annual period shows an under-reporting or underpayment by Incyte for that period in excess of five percent of the amounts properly determined, Incyte shall reimburse Prelude for its audit fees and reasonable out-of-pocket costs in connection with such audit, which reimbursement shall be made within 45 days after receiving appropriate invoices and other supporting documentation for such audit-related costs.

(g) Diligence Obligations; Post-Closing Operations.

(i) From and after the Closing Date, Incyte shall, and shall cause its Affiliates and its and their respective Licensees to, use Commercially Reasonable Efforts to Develop, seek and obtain U.S. Approval for at least one Product (which, for the avoidance of doubt, is not required to be a Product containing any specific Development Candidate). For the avoidance of doubt, provided that Incyte is otherwise in compliance with the forgoing diligence obligation, Incyte shall have no obligation to use Commercially Reasonable Efforts to Develop or Commercialize any Product containing the [\*\*\*], but may determine to progress a Product containing the [\*\*\*].

(ii) From and after the Closing Date, Incyte shall, as between the Parties, be solely responsible for, and shall bear all costs and expenses associated with, all other Development, regulatory, Manufacturing and Commercialization activities for the V617F Molecules and Products.

(iii) After the Closing, but subject to and without limiting the express obligations of Incyte under Section 2.6(g)(i), Incyte shall be entitled to conduct the Business in a manner that is in the best interests of it and its stockholders and shall have full control and sole discretion over all matters relating to the V617F Molecules and Products, and the operation of the Business; provided that Incyte shall not, and shall cause each of its Subsidiaries and Affiliates not to, directly or indirectly, take any action or omit to take any action where the primary purpose of such action or omission is to avoid achievement of any Milestone. Without limiting any express obligation of Incyte pursuant to Section 2.6(g)(i), following the Closing Date, Incyte is under no obligation (including through its use of Commercially Reasonable Efforts) to operate the Business to maximize the Contingent Payments or, if another Development Candidate is subject to appropriate Development and Commercialization activities, to further Develop or Commercialize any Product containing the First Development Candidate; provided that Incyte is otherwise in compliance with the diligence obligation in Section 2.6(g)(i). The Parties further acknowledge and agree that, despite the use by Incyte of its Commercially Reasonable Efforts in accordance with Section 2.6(g)(i), there is no assurance that any Contingent Payments will be realized by Prelude and that

neither Incyte nor any Affiliate or Representative thereof has promised or projected any specific amount. None of Incyte, its Affiliates or any of their respective Representatives owes any fiduciary duty to the Prelude with respect to the Contingent Payments. Further, the Parties acknowledge that Incyte's sole obligations with respect to any potential Contingent Payments are expressly set forth in this Section 2.6, and Incyte hereby disclaims (and Prelude hereby waives and acknowledges and agrees to such disclaimer) any obligation to take any other action, or fail to take action, with respect to the Business or the Products or any other implied covenants or obligations with respect to such Contingent Payments. Prelude agrees and acknowledges that Incyte and its Affiliates may currently or in the future research, Develop or Commercialize products that are competitive with the V617F Molecules or Products and that nothing in this Agreement shall restrict Incyte and its Affiliates from researching, Developing, acquiring or Commercializing any such products that may be competitive with any of the V617F Molecules or Products or from making any decisions with respect to such products that may adversely affect the value of the Contingent Payments. Notwithstanding anything else in this Agreement, Incyte and its Affiliates shall have no obligation to Develop or Commercialize any molecule or compound that inhibits the activity of the JAK2 tyrosine kinase Domain (JH1) [\*\*\*].

(h) Progress Reports. Following the Closing and until the earliest of (i) the date on which all Milestones have been achieved and (ii) such date as Incyte and Prelude otherwise mutually agree, Incyte shall provide Prelude, within 30 days following the end of (A) the second quarter of each calendar year and (B) each calendar year, with an semi-annual written report of the material Development work and other efforts of Incyte, its Affiliates and its and their Licensees (since the previous written report) to achieve the Milestones and its and their progress with respect thereto, as well as any progress regarding the Development and Regulatory Approval of any V617F Molecule or Product, in reasonable detail, including Trials, other testing work and regulatory activity, and the status of all INDs and Drug Approval Applications (and other applications for Regulatory Approval) for Products.

(i) Sale Transaction. Notwithstanding any other provision herein to the contrary, from the Effective Time until the end of the Net Sales Term, if Incyte or its Affiliates or permitted assignees divests or transfers all or substantially all of the Intellectual Property Rights and other rights held by Incyte or any of its Affiliates or permitted assignees in respect of the Development or Commercialization of the V617F Molecules or Products, as applicable, to any Person other than any of their respective Affiliates (any such Person, a "Third Party Transferee"), whether by merger, consolidation, asset acquisition, joint venture, exclusive license or otherwise (any such transaction, a "Product Transfer"), Incyte will cause the Third Party Transferee to assume and succeed to the obligations of Incyte set forth in this Section 2.6, including the obligations of such Third Party Transferee to use Commercially Reasonable Efforts in accordance with the terms hereof (provided, that, in such case, all references to "Incyte" in the definition of Commercially Reasonable Efforts shall refer instead to such Third Party Transferee). Incyte will not consummate any Product Transfer unless the Third Party Transferee is an entity that [\*\*\*] or otherwise with Prelude's prior consent. Incyte will provide Prelude with not less than 30 days prior written notice of the proposed Product Transfer, including the identity of the Third Party Transferee and to the extent such Third Party Transferee is not publicly listed, the relevant net worth qualifications and technical, regulatory and commercial capabilities of such Third Party Transferee. No Product Transfer will (i) amend, waive, delay, condition, reduce or otherwise impair any Contingent Payment or rights of Prelude under this Agreement, or (ii) modify any diligence standard, including Commercially Reasonable Efforts. Any attempted Product Transfer that does not comply with this Section will be void and of no effect. Incyte will not structure any Product Transfer (including via change of control, internal reorganization, escrow, or layered sublicensing) to circumvent the requirements of this Section 2.6. For clarity, the foregoing restrictions apply equally to direct and indirect transfers and to exclusive licenses that convey substantially all commercial rights to any Product in a territory that contains the United States.

## Section 2.7 Exclusivity.

(a) From and after the Closing Date and continuing until the [\*\*\*] anniversary of the Closing Date (the “Exclusivity Period”), Prelude shall not, and shall cause its Affiliates not to, directly or indirectly (including through any Third Party on their behalf), Develop, seek or obtain Regulatory Approval for, Manufacture, Commercialize or otherwise exploit any [\*\*\*].

(b) If, during the Exclusivity Period, Prelude undergoes a Change of Control with a Third Party who owns or has rights to a molecule or product and, on the date of the closing of such Change of Control, such molecule or product is being Developed or otherwise exploited and such activities would, but for the provisions of this Section 2.7(b), constitute a breach of Section 2.7(a) (a “Competing Project”), then Prelude (or its Affiliates) shall not be in breach of the exclusivity obligations of this Section 2.7 as a result of the continued conduct of activities by or on behalf of an Acquirer with respect to such Competing Project so long as, during the Exclusivity Period, Prelude shall Segregate any activities being conducted for the applicable V617F Molecules from such activities with respect to such Competing Project. Any licenses granted by Incyte to Prelude hereunder or under any other Transaction Document shall not be sublicensable, assignable or transferable by Prelude to such Acquirer for use in connection with such Competing Project except as expressly permitted under this Agreement. “Segregate” means the segregation (including through the institution and maintenance of firewalls) of Development, Commercialization or other exploitation activities relating to any Competing Project from the Development, Commercialization and other exploitation activities with respect to the applicable V617F Molecule under this Agreement, designed to ensure that: (A) no personnel involved in performing the Development, Commercialization or other exploitation of the Competing Project shall have access to non-public information relating to the Development, Commercialization or exploitation of the applicable V617F Molecule; (B) no personnel involved in performing the Development, Commercialization or exploitation of the applicable V617F Molecule who have access to non-public plans or information relating to the Development, Commercialization or exploitation of such V617F Molecule shall have access to non-public plans for information relating to the Development, Commercialization or other exploitation activities under such Competing Project; and (C) no personnel of the Acquirer involved in performing the Development, Commercialization or other exploitation of the Competing Project uses, and is not provided, in the conduct of the Competing Project (I) any Confidential Information of Incyte, (II) any Intellectual Property Rights controlled and licensed hereunder by Incyte, or (III) any non-public information relating to the research activities under this Agreement with respect to the applicable V617F Molecule, provided that for clarity, these restrictions set forth in the foregoing clauses (A),(B), and (C) will not apply to individuals involved at a senior management or executive level who are generally involved in decision-making regarding programs and products generally, and who are not involved in day-to-day activities or decision-making in connection with the applicable V617F Molecule or Competing Project, as applicable. For further clarity, inadvertent, immaterial breaches of this Section 2.7 that are cured promptly upon discovery will not constitute a breach of this Section 2.7. Nothing in this Section 2.7 prohibits Prelude or the Acquirer from pursuing any program to the extent required by applicable Law.

(c) Notwithstanding the exclusivity obligations of this Section 2.7, if, during the Exclusivity Period, Prelude acquires through an Acquisition any molecule or product the Development or other exploitation of which would, but for the provisions of this Section 2.7(c), constitute a breach of Section 2.7(a), then neither (i) such Acquisition, (ii) the Development or other exploitation of such molecule or product; or (iii) the licensing, conveyance, sublicensing or other grant of rights with respect to such molecule or product shall constitute a breach of this Section 2.7; provided that, (A) Prelude shall provide Incyte with written notice of such Acquisition promptly, but no later than [\*\*\*] prior to the consummation of such Acquisition, and (B) Prelude shall, within [\*\*\*] after the closing of such Acquisition (to the extent such [\*\*\*] period ends within the Exclusivity Period), divest such molecule or product or cease to further

Develop or exploit such molecule or product. For further clarity, inadvertent, immaterial breaches of this Section 2.7(c) that are cured promptly upon discovery will not constitute a breach of this Section 2.7(c). “Acquisition” means an acquisition by Prelude of a Third Party or a portion of the business of a Third Party (whether by merger or acquisition of all or substantially all of the stock, or of all or substantially all of the assets, of a Third Party or of any operating or business division of a Third Party or similar transaction), other than a Change of Control of Prelude.

### **ARTICLE III REPRESENTATIONS AND WARRANTIES**

Section 3.1 Representations and Warranties of Prelude. Except as set forth in the corresponding sections or subsections of the Company Schedules delivered to Incyte by Prelude concurrently with this Agreement (the “Company Schedules”), Prelude represents and warrants to Incyte as follows:

(a) Organization; Good Standing. Prelude is duly organized, validly existing and in good standing under the Laws of the jurisdiction of its organization. Prelude has the requisite power and authority to own and operate the Transferred Assets and to carry on its business as currently conducted.

(b) Authority; Execution and Delivery. Prelude has the requisite corporate power and authority to enter into this Agreement and the other Transaction Documents and to consummate the transactions contemplated hereby and thereby. The execution and delivery of this Agreement and the other Transaction Documents by Prelude and the consummation of the transactions contemplated hereby and thereby have been duly and validly authorized. This Agreement and the other Transaction Documents have been duly executed and delivered by Prelude and, assuming the due authorization, execution and delivery of this Agreement and the other Transaction Documents by Incyte, will constitute the legal, valid and binding obligation of Prelude, enforceable against it in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other similar Laws affecting creditors’ rights generally from time to time in effect and to general principles of equity (including concepts of materiality, reasonableness, good faith and fair dealing), regardless of whether considered in a proceeding in equity or at Law.

(c) Consents; No Violation. [Other than with respect to compliance with the HSR Act,] the execution and delivery of this Agreement and the other Transaction Documents do, and the consummation of the transactions contemplated hereby and thereby and the compliance with the terms hereof and thereof will, not (i) violate any Laws applicable to Prelude or the Transferred Assets in any material respect, (ii) conflict with any provision of the certificate of incorporation or by-laws (or similar organizational document) of Prelude, (iii) conflict with any material contract to which Prelude or any of its Affiliates is a party or by which it is otherwise bound, including any contract (whether or not material) related to the V617F Molecules, or (iv) require any approval, authorization, consent, license, exemption, filing or registration with any court, arbitrator or Governmental Authority, except in the case of the immediately preceding clauses (iii) and (iv) to the extent that any such violation, breach, default, termination or consent would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

(d) Title to Transferred Assets. Other than as expressly set out herein, Prelude has good and valid title to all of the Transferred Assets free and clear of all Encumbrances, other than Permitted Encumbrances.

(e) Sufficiency of Assets. The Transferred Assets constitute all of the assets which are exclusively used in or necessary for the conduct of the Business, as presently conducted in all material

respects; provided that the foregoing will not be interpreted as a representation or warranty regarding the infringement, misappropriation or other violation of any Third Party's Intellectual Property Rights, which is exclusively addressed in Section 3.1(g)(v).

(f) Actions. There is, and in the past three years has been, no Action pending or, to the actual knowledge of the Chief Executive Officer and Chief Financial Officer of Prelude after due inquiry of their direct reports ("Knowledge of Prelude"), threatened against Prelude or its Affiliates that relates to the Transferred Assets or the Business. There is no award, decision, injunction, judgment, restraining or other Order, consent or other decree, stipulation, subpoena, verdict, settlement agreement, stipulation of settlement or plea agreement that affects the Transferred Assets or the Business.

(g) Intellectual Property.

(i) Except as would not reasonably be expected to be material to Business, all Transferred Patents that are issued are subsisting, valid and, to the Knowledge of Prelude, enforceable. All payments in connection with the filing, prosecution and maintenance of the Transferred Patents have been paid in full by the applicable deadline. Prelude and its applicable Affiliates have complied in all material respects with all applicable Laws, including any duties of candor and disclosure to the United States Patent and Trademark Office and any relevant foreign office, and have not committed any inequitable conduct, in each case, in its and their prosecution, maintenance, enforcement and defense of all Transferred Patents. Each of the Transferred Patents properly identifies each inventor of the claims thereof as determined in accordance with the applicable Law of the jurisdiction in which such Patent is issued or pending.

(ii) The Transferred Patents and the Transferred Know-How constitute all Patents and Know-How owned by Prelude and its Affiliates that are Related to the Business.

(iii) Immediately following the Closing, Incyte will own or otherwise have a valid and enforceable right to use all material Intellectual Property Rights that are used or held for use in, or otherwise necessary for, the conduct of the Business; provided that the foregoing will not be interpreted as a representation or warranty regarding the infringement, misappropriation or other violation of any Intellectual Property Rights, which is exclusively addressed in Section 3.1(g)(v).

(iv) Prelude and its Affiliates solely and exclusively own all Transferred Patents and Transferred Know-How, in each case, free and clear of all Encumbrances, other than Permitted Encumbrances.

(v) Except as would not reasonably be expected to be material to the Business, to the Knowledge of Prelude, (A) the operation of the Business as currently conducted does not infringe, misappropriate or otherwise violate, and has not infringed, misappropriated or otherwise violated, any Intellectual Property Rights owned by any other person, and (B) no Person is infringing, misappropriating or otherwise violating, or has infringed, misappropriated or otherwise violated, any Transferred Patent or Transferred Know-How or any other Intellectual Property Rights used or held for use in the conduct of the Business.

(vi) Each of Prelude's and its applicable Affiliates' current and former employee, contractor and consultant who has contributed or is contributing to the creation or development of any material Intellectual Property Rights for or on behalf of the Business, including each inventor of the Transferred Patents, has executed a valid written agreement irrevocably and presently

assigning to Prelude or its applicable Affiliate all right, title and interest in and to all such Intellectual Property Rights.

(vii) Prelude and its Affiliates have not, and to the Knowledge of Prelude, no previous or joint owner has, granted any license, covenant not to sue or other right under any Transferred Patent or Transferred Know-How to any Third Party (excluding, in each case, non-exclusive licenses or similar rights granted by Prelude or any of its Affiliates in the ordinary course of business where such license or right is ancillary to the purpose of the underlying contract).

(viii) Prelude and each of its applicable Affiliates have taken commercially reasonable efforts to maintain the confidentiality of all material Prelude Know-How, and to the Knowledge of Prelude, no such material know-how has been used by or disclosed to any person, except pursuant to non-disclosure agreements which have not, to the Knowledge of Prelude, been breached in any material respect.

(ix) Except as would not reasonably be expected to be material to the Business, during the past three years, Prelude and its applicable Affiliates (A) have operated the Business in compliance with all applicable Laws regarding privacy, cybersecurity or data security in all material respects, and (B) have not received any written notice, letter or complaint alleging, or providing notice of any investigation concerning, any noncompliance with such Laws.

(h) Regulatory Matters. Prelude has not filed or obtained any INDs, Drug Approval Applications or any other regulatory documentation for any V617F Molecules in any jurisdiction. During the 12-month period ending on the Execution Date, Prelude has not received any: (i) adverse drug experience reports; (ii) material events concerning or affecting safety; or (iii) material medical complaints brought to the attention of Prelude in respect of any of the V617F Molecules.

(i) No Brokers. Prelude has not entered into any contract, agreement, arrangement or understanding with any corporation, person, partnership, entity or firm (irrespective of legal form and jurisdiction of organization) which will result in the obligation to pay any finder's fee, brokerage commission or similar payment in connection with the transactions contemplated hereby.

(j) Transferred Contracts. Other than the Transferred Contracts, there are no other material contracts currently in effect that are necessary for the operation of the Business. Each Transferred Contract is a legal, valid and binding obligation of Prelude or its Affiliate and, to the Knowledge of Prelude, each other party thereto, enforceable against Prelude or its applicable Affiliate and each other party in accordance with its terms (except as limited by applicable bankruptcy, insolvency, reorganization, moratorium or other similar Law as now or hereafter in effect relating to or affecting creditors' rights generally, and subject to the limitations imposed by general equitable principles, regardless of whether such enforceability is considered in a proceeding at Law or in equity). Prelude has not received written notice from any party claiming or alleging that Prelude has materially breached or is in material default thereunder and Prelude is not (with or without lapse of time or notice, or both) in material breach or material default thereunder. To the Knowledge of Prelude, each other party to each such contract is not in material breach or material default thereunder.

(k) Tax. Prelude has timely filed all material Tax Returns required to be filed in respect of the Transferred Assets or the Business, and all such Tax Returns (to the extent relating to the Transferred Assets or the Business) are true, correct and complete in all material respects. All Taxes due in respect of the Transferred Assets or the Business (whether or not shown on such Tax Returns) have been duly and timely

paid. There are no Encumbrances for Taxes upon any of the Transferred Assets other than Permitted Encumbrances.

(l) Exclusive Representations and Warranties. Other than the representations and warranties set forth in this Agreement (as qualified by the Company Schedules), (a) the Transferred Assets are being sold on an “as is, where is” basis as of the Closing and (b) none of Prelude, its Affiliates or any of their respective Representatives have made, or shall be deemed to have made, any other representation or warranty, express or implied, at law or in equity, in respect of the Business, the V617F Molecules, the other Transferred Assets or the Assumed Liabilities, including with respect to (i) merchantability or fitness for any particular purpose or infringement or misappropriation of Third Party rights, (ii) the Development, exploitation or Commercialization of any Product after the Closing, (iii) the probable success or profitability of any Product after the Closing or (iv) the accuracy or completeness of any (A) projections, predictions, forecasts, estimates, plans or budgets of future revenues, expenses or expenditures, future results of operations (or any component thereof), future cash flows (or any component thereof) or future financial condition (or any component thereof) that may be contained or referred to in the Company Schedules or elsewhere or (B) information, documents or materials regarding the Business or the Transferred Assets, including any information furnished or made available to Incyte, its Affiliates or their respective Representatives in any confidential information memorandum or presentation, “data room,” “virtual data room,” management presentation or in any other form in expectation of, or in connection with, the transactions contemplated hereby (the items and information referred to in the immediately preceding clauses (A) and (B) collectively, the “Evaluation Material”), or the appropriateness or suitability of any Evaluation Material for the purposes of enabling Incyte to evaluate the consummation of the transactions contemplated hereby. Any such other representations or warranties are hereby expressly disclaimed. None of Prelude, its Affiliates or any of their respective Representatives will have or be subject to any Liability to Incyte or any other Person resulting from the distribution to Incyte, its Affiliates or their respective Representatives of, or Incyte’s use of or reliance on, any Evaluation Material in expectation of the transactions contemplated hereby, unless any such Evaluation Material is expressly and specifically included in a representation or warranty set forth in this Agreement, the Company Schedules or other Transaction Documents. Incyte acknowledges and agrees that, in entering into this Agreement, it has not relied and is not relying on any representations, warranties or other statements whatsoever, whether written or oral (from or by any other Party or any Person acting on their behalf) other than those expressly set out in this Agreement and that it will not have any right or remedy arising out of any representation, warranty or other statement not expressly set out in this Agreement.

Section 3.2 Representations and Warranties of Incyte. Incyte hereby represents and warrants to Prelude as follows:

(a) Organization; Good Standing. Incyte is duly organized, validly existing and in good standing under the Laws of the State of Delaware. Incyte has the requisite corporate power and authority to carry on its business as it is currently being conducted.

(b) Authority; Execution and Delivery. Incyte has the requisite corporate power and authority to enter into this Agreement and the other Transaction Documents and to consummate the transactions contemplated hereby and thereby. The execution and delivery of this Agreement and the other Transaction Documents by Incyte and the consummation of the transactions contemplated hereby and thereby have been duly and validly authorized. This Agreement and the other Transaction Documents have been duly executed and delivered by Incyte and, assuming the due authorization, execution and delivery of this Agreement and the other Transaction Documents by Prelude, constitutes the legal, valid and binding obligation of Incyte, enforceable against Incyte in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other similar Laws affecting

creditors' rights generally from time to time in effect and to general principles of equity (including concepts of materiality, reasonableness, good faith and fair dealing), regardless of whether considered in a proceeding in equity or at Law.

(c) Consents; No Violations. [Other than with respect to compliance with the HSR Act,] the execution and delivery of this Agreement and the other Transaction Documents do, and the consummation of the transactions contemplated hereby and thereby and the compliance with the terms hereof and thereof will, not (i) violate any Laws applicable to Incyte in any material respect, (ii) conflict with any provision of the certificate of incorporation or by-laws of Incyte, (iii) conflict with any material contract to which Incyte is a party or by which it is otherwise bound or (iv) require any approval, authorization, consent, license, exemption, filing or registration with any court, arbitrator or Governmental Authority, except in the cases of clause (iii), where the violation, breach, conflict, default, acceleration, or failure to give notice would not have a material adverse effect on Incyte's ability to consummate the transactions contemplated hereby.

(d) Actions. There is no Action pending or, to the knowledge of Incyte, threatened against Incyte or any of its Affiliates which, if adversely determined, would materially interfere with the ability of Incyte to perform its obligations hereunder or challenge or seek to prevent, enjoin or otherwise delay the transactions contemplated hereby.

(e) No Brokers. Incyte has not entered into any agreement, arrangement or understanding with any Person or firm which will result in the obligation to pay any finder's fee, brokerage commission or similar payment in connection with the transactions contemplated hereby.

(f) Sufficiency of Funds. Incyte has, and at the Closing will have, available cash resources in amounts sufficient to (a) pay the Closing Cash Consideration payable hereunder and to satisfy all other payments required by this Agreement, whether payable before, at or after the Closing and including any Contingent Payment, (b) pay any related fees, costs and expenses incurred by Incyte or its Affiliates in connection with the transactions contemplated hereby and (c) otherwise consummate the transactions contemplated hereby.

(g) Exclusive Representations and Warranties. Other than the representations and warranties set forth in this Agreement, none of Incyte, its Affiliates or any of their respective Representatives have made, or shall be deemed to have made, any other representation or warranty, express or implied, at law or in equity, in respect of the transactions contemplated hereby, including with respect to (i) merchantability or fitness for any particular purpose or infringement or misappropriation of Third Party rights, (ii) the Development, exploitation or Commercialization of any Product after the Closing or (iii) the probable success or profitability of any Product after the Closing. Prelude acknowledges and agrees that, in entering into this Agreement, it has not relied and is not relying on any representations, warranties or other statements whatsoever, whether written or oral (from or by any other Party or any Person acting on their behalf) other than those expressly set out in this Agreement and that it will not have any right or remedy arising out of any representation, warranty or other statement not expressly set out in this Agreement.

## **ARTICLE IV COVENANTS**

### Section 4.1 [Interim Operating Covenants.

(a) Except as otherwise expressly required or permitted by this Agreement, Prelude covenants and agrees that, during the period from the Execution Date until the Closing, unless Incyte shall otherwise

approve in writing (not to be unreasonably withheld, conditioned or delayed), and except as required by applicable Laws or as contemplated by this Agreement, the Business shall be conducted in the ordinary course consistent with past practice and, to the extent consistent therewith, solely as it relates to the Business, Prelude shall, and shall cause its Affiliates to use their respective commercially reasonable efforts to preserve their business organizations intact and maintain the Business' existing relations with Governmental Authorities, grant providers, suppliers, creditors, lessors and employees and other parties with whom the Business has a material business relationship.

(b) Without limiting the generality of, and in furtherance of, the foregoing, from the Execution Date until the Closing, except (x) as otherwise expressly required by applicable Law or this Agreement or (y) as Incyte may approve in writing (not to be unreasonably withheld, conditioned or delayed), Prelude shall not, and shall not permit its Subsidiaries to:

(i) adopt any change in the organizational documents of Prelude or any of its Subsidiaries that would reasonably be expected to prevent, materially delay or materially impair the consummation of the transactions contemplated hereby;

(ii) enter into any agreements or arrangements imposing material changes or restrictions on the Transferred Assets or the Business;

(iii) transfer, sell, lease, license, mortgage, pledge, surrender, encumber, divest, cancel, abandon or allow to lapse or expire or otherwise dispose of any of the Transferred Assets;

(iv) sell, assign or transfer, license, subject to an Encumbrance (other than a Permitted Encumbrance), abandon, allow to lapse or otherwise dispose of any Transferred Asset;

(v) fail to use good-faith efforts to make any additional capital expenditure otherwise required to operate the Business in substantially the same manner as presently conducted;

(vi) enter into any contract that would have been material to the Business had it been entered into prior to the Execution Date;

(vii) amend, modify, fail to renew or terminate any Transferred Contract;

(viii) amend, modify, cancel or waive any debts or claims held by it that are related to the Transferred Assets or Related to the Business;

(ix) waive any material rights Related to the Business;

(x) settle any Action Related to the Business or the Transferred Assets or any other material obligation or liability of Prelude or any of its Subsidiaries Related to the Business or the Transferred Assets;

(xi) fail to pay or satisfy when due any material account payable or other material liability Related to the Business or the Transferred Assets, other than any such liability that is being contested in good faith by Prelude or any of its Subsidiaries;

(xii) fail to keep current and in full force and effect, or to apply for or renew, any material permit, approval, authorization, consent, license, registration or certificate issued by any Governmental Authority Related to the Business or related to the Transferred Assets;

(xiii) initiate any new Trial or expand or materially amend any existing Trial (including any pre-clinical study intended to support a Trial), or prepare, submit, file, or cause to be submitted to any Regulatory Authority (including the FDA) any IND or any Regulatory Materials, in each case with respect to any Development Candidate or any of the V617F Molecules; or

(xiv) agree, authorize or commit to do any of the foregoing.

(c) Nothing contained in this Agreement is intended to give Incyte, directly or indirectly, the right to control or direct the operations of the Business or the V617F Molecules or the other Transferred Assets prior to the Closing Date. Prior to the Closing Date, Prelude shall exercise, consistent with the terms and conditions of this Agreement, complete control and supervision over the operations of the Business or the V617F Molecules and the other Transferred Assets.

Section 4.2 Cooperation and Efforts. Upon the terms and subject to the conditions set forth in this Agreement, the Parties shall cooperate with each other and use (and shall cause their respective controlled Affiliates to use) their respective commercially reasonable efforts to take or cause to be taken all actions reasonably necessary or advisable on their part under this Agreement to consummate the transactions contemplated hereby as promptly as reasonably practicable and not to take any action after the Execution Date that would reasonably be expected to prevent, materially delay or materially impair the consummation of the transactions contemplated hereby.

Section 4.3 Status Updates. Subject to applicable Laws and as required by any Governmental Authority, the Parties shall each keep the other apprised of the status of matters relating to the consummation of the transactions contemplated hereby, including promptly furnishing the other with copies of notices or other communications (or where no such copies are available, a reasonably detailed written description thereof) received by Prelude or Incyte, as the case may be, or any of its Subsidiaries, from any Third Party or any Governmental Authority with respect to the transactions contemplated hereby. In furtherance and not in limitation of any other provision of this Agreement, to the extent permitted by applicable Law, prior to the Closing, (a) Prelude shall keep Incyte reasonably informed on a current basis of any material developments (clinical or otherwise) with respect to the V617F Molecules and of any material discussions or negotiations with the FDA or any other Governmental Authority regarding Prelude's regulatory strategy with respect to the V617F Molecules, and shall provide copies of material information to Incyte, in each case, relating to the V617F Molecules, and (b) without limiting the generality of the foregoing, Prelude shall promptly inform Incyte of, and provide Incyte with a reasonable opportunity to review, any pre-submissions or submissions, substantive correspondence or other material communications made by or on behalf of Prelude with respect to the Business or the V617F Molecules to, between or with the FDA or any other Governmental Authority, and consider in good faith Incyte's comments to or in connection with, any such submissions, correspondence or communication.

Section 4.4 Submission of Filings and Notices.

(a) Exchanging Information. The Parties shall each, upon request by the other, furnish the other with all information concerning itself, its Subsidiaries, directors, officers and members and stockholders and such other matters as may be reasonably necessary or advisable in connection with any statement, filing, notice or application made by or on behalf of Prelude, Incyte or any of their respective Subsidiaries to any Governmental Authority in connection with the transactions contemplated hereby.

(b) Initial Submissions. The Parties shall prepare and file as promptly as reasonably practicable all documentation to effect all necessary notices, reports and other filings and to obtain as promptly as practicable all consents, clearances, registrations, approvals, permits and authorizations

necessary or advisable to be obtained from any Governmental Authority in order to consummate the transactions hereby. Without limiting the foregoing, each of Prelude and Incyte shall make its respective filing pursuant to the HSR Act with respect to the transactions contemplated hereby as promptly as reasonably practicable after the Execution Date and no later than ten (10) Business Days after the Execution Date. Incyte shall bear 100% of the filing fees associated with any filings under the HSR Act and any other filings made to any Governmental Authority. The Parties shall use their respective reasonable best efforts to obtain early termination of the waiting period with respect to the transactions contemplated hereby under the HSR Act.]

(c) Subsequent Submissions. The Parties shall promptly provide all documents requested by any Governmental Authority to the extent reasonably necessary or advisable to obtain as promptly as practicable all consents, registrations, approvals, permits and authorizations necessary or advisable to be obtained from such Governmental Authority in order to consummate the transactions contemplated hereby.

(d) Conduct of Interactions with Governmental Authorities. Subject to applicable Laws relating to the exchange of information, Incyte and Prelude shall have equal rights to direct the strategy with respect to all matters with any Governmental Authority, and each Party shall have the right to review and approve in advance any substantive communications with any Governmental Authority in connection with the transactions contemplated hereby. Neither Party shall permit any of its officers or any other Representatives or agents to participate in any meeting with any Governmental Authority in respect of any filing, investigation or other inquiry relating to the transactions contemplated hereby unless it consults with the other Party in advance and, to the extent permitted by such Governmental Authority, gives the other Party the opportunity to attend and participate thereat. Nevertheless, each Party and each Representative thereof shall respond to all inquiries in a manner which he, she or it considers true and correct. Prelude and Incyte, and their respective Representatives, shall not agree to any actions, restrictions or conditions with respect to obtaining any consents, registrations, approvals, permits, expirations of waiting periods or authorizations in connection with the transactions contemplated hereby without the prior written consent of the other Party. During the period commencing from the Execution Date and continuing until the earlier to occur of the termination of this Agreement pursuant to Section 6.1 and the Closing, neither Party will acquire or agree to acquire by merging or consolidating with, purchasing a portion of the assets of, exclusively licensing, or acquiring in any other manner, any business of any Person or other business organization or division thereof, if the entering into of a definitive agreement relating to, or the consummation of, such transaction would reasonably be expected to prevent, delay or impede the consummation of the transactions contemplated hereby or impose any material delay in the obtaining of, or increasing the risk of not obtaining, the expiration or termination of any applicable waiting period under the HSR Act.

(e) Remedies. Notwithstanding anything to the contrary in this Agreement, nothing in this Agreement, including Section 4.2, shall require Incyte or any of its Affiliates to:

- (i) proffer to, agree to or effect any sale, divestiture, lease, license, transfer, disposition, encumbrance or hold-separate arrangements, before or after the Closing, any assets of Incyte or any of its Affiliates (or consent thereto) or any Transferred Assets;
- (ii) proffer to, agree to or implement any changes to (including through a licensing arrangement), or any restrictions on or other impairment of, Incyte's ability to use, own, operate or take any other actions with respect to any assets of Incyte or any of its Affiliates or any Transferred Assets; or

(iii) take any action to overturn, defend against or oppose any action by any Governmental Authority to prohibit the transactions contemplated hereby or prevent consummation of the transactions contemplated hereby prior to the Outside Date.

Section 4.5 Pre-Closing Access. Subject to applicable Law, upon reasonable advance notice, Prelude shall, and shall cause its Subsidiaries to, afford Incyte's officers and other authorized Representatives reasonable access, during normal business hours throughout the period prior to the Closing, to its employees, properties, books, contracts and records, in each case to the extent relating to the Business and Transferred Assets so long as such access does not unreasonably interfere with the normal operations of Prelude and its Subsidiaries, and, during such period, Prelude shall, and shall cause its Subsidiaries to, furnish promptly to Incyte all information concerning the Business as Incyte may reasonably request; provided that the foregoing shall not require Prelude (a) to permit any inspection, or to disclose any information, that in the reasonable judgment of Prelude would result in the disclosure of any trade secrets of Third Parties or violate any of its obligations with respect to confidentiality if Prelude shall have used commercially reasonable efforts to obtain the consent of such Third Party to such inspection or disclosure or if any Law applicable to Prelude requires it to restrict or prohibit access to such information or (b) to disclose any privileged information of Prelude or any of its Subsidiaries. All requests for information made pursuant to this Section 4.5 shall be directed to Persons designated by Prelude. All such information shall be governed by the terms of the Confidentiality Agreements, the terms of which are hereby incorporated herein by reference.<sup>5</sup>

Section 4.6 Post-Closing Access. Subject to applicable Law, from and after the Closing, Incyte shall (a) retain all books, ledgers, files, reports, plans, operating records and any other material documents pertaining to the Business in existence at the Closing that are required to be retained under current retention policies (collectively, the "Records") for a period of four years from the Closing Date, and (b) provide Prelude or its Representatives at Prelude's expense with reasonable access without hindering the normal operations of the Business (solely for the purpose of inspection and copying), during normal business hours, and upon reasonable advance notice and under the supervision of Incyte's personnel, to the Records with respect to periods or occurrences prior to the Closing Date. Notwithstanding the foregoing provisions of this Section 4.6, Incyte may withhold access, documents or information that in the reasonable judgment of Incyte would result in the disclosure of any trade secrets of Third Parties or violate any of its obligations with respect to confidentiality if Incyte shall have used commercially reasonable efforts to obtain the consent of such Third Party to such inspection or disclosure or if any Law applicable to Incyte requires it to restrict or prohibit access to such information.

Section 4.7 Third-Party Consents. Notwithstanding anything to the contrary herein, this Agreement shall not constitute an agreement to assign or transfer any Transferred Contract or any other Transferred Asset that is not assignable or transferable without the consent of any Third Party under any contracts or other arrangements existing as of the Closing Date to which Prelude or any of its Affiliates are party or otherwise bound and the Parties shall use reasonable best efforts to obtain any such consents; provided that neither Prelude nor any of its Affiliates shall have any obligation to agree to make or make any payments or other concessions, unless and until Incyte confirms in writing that it will reimburse Prelude and its Affiliates for the entirety of such payments. With respect to any Transferred Contract or any other Transferred Asset that is not assigned or transferred to Incyte at the Closing by reason of this Section 4.7 (a "Nonassigned Asset"), for a period beginning on the Closing Date and ending on the earlier of (i) the time such requisite consent is obtained and the foregoing is transferred and assigned to Incyte and (ii) the twelve (12) month anniversary of the Closing Date (or such other date agreed by the Parties), (A) Prelude

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<sup>5</sup> Note to Draft: To be included in this Agreement based on Incyte's determination of whether an HSR filing is necessary prior to the execution of this Agreement.

shall, and shall cause its Affiliates to, use commercially reasonable efforts to provide to Incyte substantially comparable benefits thereof and shall enforce, at the request of and for the benefit of Incyte (at Incyte's sole cost and expense), any rights of Prelude or its Affiliates arising thereunder against any Third Party, including the right to seek any available remedies or to elect to terminate in accordance with the terms thereof upon the advice of Incyte and (B) any burdens relating to the Nonassigned Asset shall inure to Incyte. As a condition to Prelude or one of its Affiliates providing Incyte with the benefits of any Nonassigned Asset, subject to applicable Law, Incyte shall perform, at the direction of Prelude, the obligations of Prelude or any of its Affiliates thereunder. Prelude shall hold in trust and pay to Incyte promptly upon receipt thereof, all income, proceeds and other monies received by Prelude or any of its Affiliates in connection with any Nonassigned Asset (net of any Taxes and any other costs, fees and other expenses imposed upon or incurred by Prelude or any of its Affiliates in respect of the receipt of such income, proceeds and other monies) in connection with the arrangements under this Section 4.7. Once authorization, approval, consent or waiver for the sale, assignment, sublease, transfer, conveyance or delivery of any Transferred Contract or any other Transferred Asset not sold, assigned, subleased, transferred, conveyed or delivered at the Closing is obtained, Prelude shall assign, transfer, convey and deliver such asset to Incyte at no additional cost.

Section 4.8 Commingled Contracts. For a period of 12 months after the Closing (or such other date agreed by the Parties), each of the Parties shall, and shall cause their respective Affiliates to, use its reasonable best efforts to: (a) cause the counterparties to any contract, contract right, bid, tender, purchase order or other agreement relating to (x) the Transferred Assets and (y) one or more other businesses of Prelude or any of its Affiliates set forth in Section 4.8 of the Company Schedules (each, a "Commingled Contract") to enter into new contracts with Incyte or its designated Affiliate in order for Incyte or its designated Affiliate to receive the benefits and burdens of such Commingled Contract (each such new contract, a "New Contract"), or (b) if practicable, assign to Incyte or its designated Affiliate the benefits and obligations under such Commingled Contract as they relate to the Products or any other Transferred Asset (each, a "Relevant Part"). Until such time as a New Contract is executed or such benefits and obligations under such Commingled Contract are assigned to Incyte or its designee, the Parties shall use and cause their respective Affiliates to use their commercially reasonable efforts to secure an alternative arrangement reasonably satisfactory to both Parties under which Incyte would, in compliance with applicable Law, obtain the benefits and burdens associated with the applicable Commingled Contract with respect to the Products and the other Transferred Assets, as applicable. For clarity, in no event shall any Party or any of its respective Affiliates be required to pay any additional consideration in connection with compliance with its obligations under this Section 4.8, or to commence, defend or participate in any Action in connection therewith or to offer or grant any accommodation (financial or otherwise) to any Third Party in connection therewith.<sup>6</sup>

#### Section 4.9 Taxes.

(a) If the Payer determines that any withholding is required under applicable Law in respect of any payments under this Agreement, it shall provide notice to the Payee of its intent to withhold at least 10 days prior to withholding any amount pursuant to this Section 4.9 (or otherwise as a soon as reasonably practicable). If a Party determines that applicable Law requires withholding of income Taxes or other Taxes imposed upon payments by such Party (the "Payer") to the other Party (the "Payee"), then, the Payer shall provide notice to the Payee of its intent to withhold at least 10 days prior to withholding any amount pursuant to this Section 4.9 (or otherwise as a soon as reasonably practicable) and, upon Payee's request, use commercially reasonable efforts to minimize or eliminate any Taxes which may be levied on any payments, including by supporting the Payee in obtaining the benefit of any relevant Tax treaties. If either

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<sup>6</sup> Note to Draft: Subject to diligence if there are any applicable contracts.

Party is entitled under any applicable Tax treaty to a reduction of the rate of, or the elimination of, applicable withholding Tax, it may deliver to the other Party or the appropriate Governmental Authority (with the assistance of the other Party to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the other Party of its obligation to withhold Tax, and the other Party shall apply the reduced rate of withholding Tax, or dispense with withholding Tax, as the case may be. If, in accordance with the foregoing, a Party withholds any amount, it shall make timely payment to the proper taxing authority of the withheld amount and send to the other Party proof of such payment within 30 days following such latter payment. To the extent such amounts are so deducted or withheld and paid over to the proper taxing authority by a Party, such deducted or withheld amounts shall be treated for all purposes of this Agreement as having been paid to the other Party.

(b) All transfer, documentary, sales, use, stamp, recording, registration and other similar Taxes and fees (including any penalties and interest) incurred in connection with the sale and purchase of the Transferred Assets described in Section 2.1 or assumption of the Assumed Liabilities described in Section 2.2 (collectively, “Transfer Taxes”) shall be borne 50% by Prelude and 50% by Incyte. The Parties shall cooperate in preparing, executing and filing any Transfer Tax returns. Each of the Parties will use its reasonable best efforts to avail itself of any available exemptions from any such Transfer Taxes.

(c) As soon as reasonably practical following the Closing Date, Incyte shall deliver to Prelude a written schedule prepared in good faith by Incyte, that allocates the total consideration (as determined for U.S. federal income tax purposes, including Assumed Liabilities) paid by Incyte to Prelude pursuant to this Agreement, the Option Agreement and any other Transaction Document in connection with the sale and purchase of the Transferred Assets described in Section 2.1 or the assumption of the Assumed Liabilities described in Section 2.2 (the “Consideration”) among the Transferred Assets for Prelude’s review (an “Allocation Schedule”). Such Allocation Schedule shall be prepared in accordance with Section 1060 of the Internal Revenue Code of 1986, as amended. Prelude shall have 60 days after Incyte’s delivery to Prelude of the Allocation Schedule during which to notify Incyte in writing of any dispute of any allocation, item, calculation or other matter contained in the Allocation Schedule, (an “Allocation Dispute Notice”). In the event that Prelude delivers an Allocation Dispute Notice to Incyte within such sixty (60)-day period, Prelude and Incyte shall cooperate in good faith to endeavor to resolve any dispute(s) with respect to the Allocation Schedule within 30 days after Prelude’s delivery of the Allocation Dispute Notice. If, following delivery of such Allocation Dispute Notice, Prelude and Incyte agree in writing (which shall be signed by both Incyte and Prelude) to a resolution of any items under dispute, such resolution shall be final and binding on Incyte and Prelude. To the extent Incyte and Prelude fail to reach an agreement regarding any such dispute(s) despite good faith cooperation, each party may use its own allocation. If Prelude does not notify Incyte of any such dispute within 60 days after receiving the Allocation Schedule, Prelude shall be deemed to agree with the Allocation Schedule, which shall be treated as final and binding on Incyte and Prelude. To the extent that the Consideration is subsequently adjusted, Incyte and Prelude shall revise and amend the Allocation Schedule, with any disputes regarding such amendment being resolved under the same procedures above as apply to the initial Allocation Schedule, *mutatis mutandis*. The final Allocation Schedule shall be binding on Incyte and Prelude for all Tax reporting purposes and neither Incyte nor Prelude (nor any of their respective Affiliates) shall take any position (whether in audits, Tax Returns or otherwise) that is inconsistent with such final Allocation Schedule unless required to do so by applicable Tax Law; provided, that nothing contained herein shall prevent Incyte or Prelude from settling any proposed deficiency or adjustment by any Governmental Authority based upon or arising out of the final Allocation Schedule, and neither Incyte nor Prelude shall be required to litigate before any court any proposed deficiency or adjustment by any Governmental Authority challenging such final Allocation Schedule.

Section 4.10 Covenant Not to Sue. Effective upon the Closing, Prelude and its Affiliates shall not, and shall not authorize any Third Party to, file a claim or commence a suit, action or proceeding for damages or for an injunction or injunction, based upon an assertion of infringement of any Prelude Blocking Patent against Incyte or any of its Affiliates or Licensees, or its or their contractors and customers based on the Development, Manufacture or Commercialization of any product that contains a V617F Molecule as it existed as of the Closing. “Prelude Blocking Patent” means any Patent that [\*\*\*].

Section 4.11 Wrong Pockets; Refunds and Remittances.

(a) Following the Closing, if either Party discovers that any assets held by Prelude or any of its Affiliates are Transferred Assets or otherwise Intellectual Property Rights owned by Prelude or any of its Affiliates that is Related to the Business, but were not transferred to Incyte as part of the consummation of the transactions contemplated hereby, then any such assets shall be deemed to have been held in trust by Prelude or its Affiliates for Incyte, and Prelude shall, and shall cause its Affiliates to, promptly transfer, assign and convey such assets to Incyte without any additional consideration therefor free and clear of all Encumbrances (other than Permitted Encumbrances).

(b) Following the Closing, if either Party discovers that any assets that have been transferred by Prelude to Incyte are not Transferred Assets, then any such assets shall be deemed to have been held in trust by Incyte for Prelude, and Incyte shall, and shall cause its Affiliates to, promptly transfer, assign and convey such assets to Prelude without any consideration therefor free and clear of all Encumbrances (other than Permitted Encumbrances).

(c) From and after the Closing, if Prelude receives any property, refund or other amount which is a Transferred Asset or is otherwise properly due and owing to Incyte in accordance with the terms of this Agreement, Prelude shall promptly remit, or shall cause to be remitted, such property or amount to Incyte (net of any Taxes imposed on Prelude or its Affiliates with respect to the receipt of such amounts). After the Closing, if Incyte or any of its Affiliates receives any property, refund or other amount which is an Excluded Asset or is otherwise properly due and owing to Prelude in accordance with the terms of this Agreement, Incyte shall promptly remit, or shall cause to be remitted, such property or amount to Prelude or Prelude’s designee (net of any Taxes imposed on Incyte or its Affiliates with respect to the receipt of such amounts).

**ARTICLE V  
CLOSING CONDITIONS<sup>7</sup>**

Section 5.1 Conditions to Each Party’s Obligation to Consummate the Transactions. The obligation of each Party to consummate the transactions contemplated hereby is subject to the satisfaction or waiver in writing by Incyte and Prelude at or prior to the Closing of each of the following conditions:

(a) [HSR Approval. (i) The waiting period (and any extension thereof) applicable to the consummation of the transactions contemplated hereby under the HSR Act shall have expired or been terminated and (ii) any timing agreement(s) with a Governmental Authority applicable to the consummation of the transactions contemplated hereby shall have expired or otherwise not prohibit consummation of the transactions contemplated hereby.]

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<sup>7</sup> Note to Draft: To be updated prior to the execution of this Agreement based on Incyte’s determination of whether an HSR approval or any other governmental filings are needed at such time.

(b) Orders and Litigation. No court, arbitrator, mediator or other Governmental Authority of competent jurisdiction shall have enacted, enforced, entered, issued or promulgated any Order or Law (whether temporary, preliminary or permanent) that is in effect and has the effect of (i) making the transactions contemplated hereby illegal or otherwise restraining or prohibiting consummation of the transactions contemplated hereby or (ii) causing the transactions contemplated hereby to be rescinded following their consummation, and no Action brought by any Governmental Authority or any other Person challenging or seeking to restrain or prohibit the consummation of the transactions contemplated hereby shall be pending or threatened.

Section 5.2 Conditions to Obligations of Incyte.<sup>8</sup> The obligations of Incyte to consummate the transactions contemplated hereby is also subject to the satisfaction or waiver in writing by Incyte at or prior to the Closing of the following conditions:

(a) Representations and Warranties of Prelude.

(i) The representations and warranties in Section 3.1(a), Section 3.1(b) and Section 3.1(i) shall be true and correct in all respects as of the Execution Date and as of the Closing as though made on and as of such date and time (except to the extent that any such representation and warranty expressly speaks as of an earlier date, in which case such representation and warranty shall be true and correct as of such earlier date).

(ii) The Non-Fundamental Representations shall be true and correct (without giving effect to any “materiality” or “Material Adverse Effect” qualifiers contained therein) as of the Execution Date and as of the Closing as though made on and as of such date and time (except to the extent that any such representation and warranty expressly speaks as of an earlier date, in which case such representation and warranty shall be true and correct as of such earlier date), except where the failure of any such representations and warranties to be so true and correct would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect or prevent, materially delay or materially impair the consummation of the transactions contemplated hereby.

(b) Performance of Obligations of Prelude. Prelude shall have performed and complied in all material respects with all covenants required to be performed by it under this Agreement on or prior to the Closing Date.

(c) Closing Certificate. Incyte shall have received at the Closing a certificate signed on behalf of Prelude by a duly authorized officer of Prelude (solely in his or her capacity as such and not in his or her personal capacity, and without personal liability), certifying that the conditions set forth in Section 5.2(a), Section 5.2(b) and Section 5.2(e) have been satisfied.

(d) Receipt of Deliverables. Incyte shall have received all items required to be delivered to Incyte pursuant to Section 2.5(a) at or prior to the Closing.

(e) No Material Adverse Effect. Between the Execution Date and the Closing Date, there shall not have occurred any Material Adverse Effect.

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<sup>8</sup> Note to Draft: Additional closing conditions, including any third party consents, are subject to diligence.

Section 5.3 Conditions to Obligations of Prelude. The obligation of Prelude to consummate the transactions contemplated hereby is also subject to the satisfaction or waiver in writing by Prelude at or prior to the Closing of the following conditions:

(a) Representations and Warranties of Incyte.

(i) The representations and warranties in Section 3.2(a), Section 3.2(b) and Section 3.2(e) shall be true and correct in all respects as of the Execution Date and as of the Closing as though made on and as of such date and time (except to the extent that any such representation and warranty expressly speaks as of an earlier date, in which case such representation and warranty shall be true and correct as of such earlier date).

(ii) The other representations and warranties of Incyte contained in Section 3.2 shall be true and correct (without giving effect to any “materiality” qualifiers contained therein) as of the Execution Date and as of the Closing Date as though made on and as of such date and time (except to the extent that any such representation and warranty speaks as of an earlier date, in which case such representation and warranty shall be true and correct as of such earlier date), except where the failure of any such representation and warranty to be so true and correct would not, individually or in the aggregate, reasonably be expected to prevent, materially delay or materially impair the ability of Incyte to consummate the transactions contemplated hereby.

(b) Performance of Obligations of Incyte. Incyte shall have performed and complied with each of the covenants required to be performed by it under this Agreement on or prior to the Closing Date in all material respects.

(c) Closing Certificate. Prelude shall have received at the Closing a certificate signed on behalf of Incyte by a duly authorized officer of Incyte (solely in his or her capacity as such and not in his or her personal capacity, and without personal liability), certifying that the conditions set forth in Section 5.3(a) and Section 5.3(b) have been satisfied.

(d) Receipt of Deliverables. Prelude shall have received all items required to be delivered to Prelude pursuant to Section 2.5(b) at or prior to the Closing.

## ARTICLE VI TERMINATION

Section 6.1 Termination. This Agreement may be terminated at any time prior to the Closing:

(a) by written agreement of the Parties;

(b) by either Party, by giving written notice of such termination to the other Party, if:

(i) the Closing shall not have occurred on or prior to the Outside Date; provided, that the right to terminate this Agreement pursuant to this Section 6.1(b)(i) shall not be available to any Party if such Party has breached in any material respect its obligations under this Agreement in any manner that shall have proximately contributed to the failure of the Closing to have occurred on or prior to the Outside Date; or

(ii) any Order permanently restraining, enjoining or otherwise prohibiting the consummation of the transactions contemplated hereby shall become final and non-appealable;

provided, that the right to terminate this Agreement pursuant to this Section 6.1(b)(ii) shall not be available to any Party if such Party has breached in any material respect its obligations under this Agreement in any manner that proximately contributed to such Order becoming final and non-appealable;

(c) by Prelude (upon written notice from Prelude to Incyte), if Incyte shall have breached or failed to perform in any material respect any of its covenants or other agreements contained in this Agreement, or any of its representations and warranties shall have become untrue after the Execution Date, which breach or failure to perform or be true (i) would give rise to the failure of a condition set forth in Section 5.1 or Section 5.3 and (ii) is not curable or, if curable, is not cured within the earlier of (A) 30 days after written notice thereof is given by Prelude to Incyte and (B) the Outside Date; provided, that Prelude shall not have the right to terminate this Agreement pursuant to this Section 6.1(c) if Prelude is then in material breach of any of its representations, warranties, covenants or other agreements hereunder such that it would give rise to the failure of a condition set forth in Section 5.1 or Section 5.2; or

(d) by Incyte (upon written notice from Incyte to Prelude), if Prelude shall have breached or failed to perform in any material respect any of its covenants or other agreements contained in this Agreement, or any of its representations and warranties shall have become untrue after the Execution Date, which breach or failure to perform or be true (i) would give rise to the failure of a condition set forth in Section 5.1 or Section 5.2, respectively and (ii) is not curable or, if curable, is not cured within the earlier of (A) 30 days after written notice thereof is given by Incyte to Prelude and (B) the Outside Date; provided, that Incyte shall not have the right to terminate this Agreement pursuant to this Section 6.1(d) if Incyte is then in material breach of any of its representations, warranties, covenants or other agreements hereunder such that it would give rise to the failure of a condition set forth in Section 5.1 or Section 5.3.

Section 6.2 Effect of Termination and Abandonment. In the event of termination of this Agreement pursuant to Article VI, this Agreement shall become void and of no effect with no liability to any Person on the part of any Party (or of any of its Representatives); provided, however, that no such termination shall relieve any Party (whether or not the terminating Party) of any liability or damages to any other Party resulting from willful and material breach of this Agreement, and the provisions set forth in this Section 6.2 and Article VIII and the and the Confidentiality Agreements shall survive the termination of this Agreement.

## **ARTICLE VII INDEMNIFICATION**

Section 7.1 Survival. All representations and warranties of Prelude and Incyte contained herein or made pursuant hereto shall survive the Closing Date and shall remain operative and in full force and effect for a period of twelve (12) months following the Closing Date; provided, however, that the representations and warranties in Section 3.1(a), Section 3.1(b), Section 3.2(a) and Section 3.2(b) shall survive until expiry of the applicable statute of limitations. The survival date applicable to the covenants and agreements set forth in this Agreement shall be (a) with respect to covenants and agreements that require performance in full prior to the Closing, the Closing Date, and (b) with respect to covenants and agreements that by their terms are required to be performed, in whole or in part, after the Closing, the date on which such covenants and agreements have been fully performed or otherwise satisfied in accordance herewith.

Section 7.2 Indemnification by Prelude. Subject to Section 7.4, Prelude shall indemnify, defend, hold harmless and reimburse Incyte, its Affiliates, and their respective directors, officers, agents, employees, successors and assigns (each, an "Incyte Indemnified Party") for, from and against any and all

claims, obligations and other Losses arising out, relating to, or occurring as a result of or in connection with: (a) any breach by Prelude of any representation or warranty made by it contained in this Agreement; (b) any failure by Prelude to comply with any covenants, agreements or obligations of Prelude contained in this Agreement; and (c) any Excluded Liability.

Section 7.3 Indemnification by Incyte. Subject to Section 7.4, Incyte shall indemnify, defend, hold harmless and reimburse Prelude, its Affiliates, and their respective directors, officers, agents, employees, successors and assigns (each, a “Prelude Indemnified Party”) for, from and against any and all claims, obligations and other Losses arising out of, relating to, or occurring as a result of or in connection with: (a) any breach by Incyte of any representation or warranty made by it contained in this Agreement; (b) any failure by Incyte to comply with any covenants, agreements or obligations of Incyte contained in this Agreement that are to be performed at or prior to the Closing; and (c) any Assumed Liability.

Section 7.4 Limitations.

(a) The aggregate amount for which Prelude and its Affiliates is liable pursuant to Section 7.2(a) (breaches of representations and warranties) with respect to Non-Fundamental Representations shall not exceed \$[\*\*\*] in the aggregate, provided that (i) such liability cap shall not apply to any liability of Prelude for Fraud on the part of Prelude and (ii) the cumulative indemnification obligations of Prelude under this Agreement shall in no event exceed the amount of the Closing Cash Consideration *plus* the amount of any Contingent Payments actually received by Prelude.

(b) None of Prelude nor any of its Affiliates shall be liable as a result of or in connection with any breach by Prelude of any Non-Fundamental Representation unless and until the amount of Losses arising from any matter or series of matters relating to the same underlying fact, circumstance, action or event exceeds \$[\*\*\*] and unless the aggregate amount of such Losses for claims for any breaches of Non-Fundamental Representations exceeds \$[\*\*\*] (in which case Incyte shall only be entitled to claim the excess).

(c) The amount of any Losses for which either Prelude or Incyte, as the case may be, is liable shall be reduced by the amount of any insurance proceeds actually paid to the Incyte Indemnified Party or the Prelude Indemnified Party (net of any documented costs and expenses incurred to obtain the recovery), as applicable. If the Indemnified Party receives any amounts under applicable insurance policies or from any other Person alleged to be responsible for any Losses subsequent to an indemnification payment by the Indemnifying Party, then such Indemnified Party shall promptly reimburse the Indemnifying Party for any payment made or expense incurred by such Indemnifying Party in connection with providing such indemnification up to the amount received by the Indemnified Party, net of any expenses incurred by such Indemnified Party in collecting such amount.

(d) No Losses shall be determined or increased based on any multiple of any financial measure (including earnings, sales or other benchmarks) that might have been used by Incyte in the valuation of the Business or the Transferred Assets. In no event shall either Party or any of its Affiliates be liable under this Agreement or common law for any consequential, special or incidental or punitive Loss or damage (whether for loss of current or future profits, loss of enterprise value or otherwise); provided that the foregoing does not limit any of the obligations or liability of either Party or its Affiliates under Section 7.2 and Section 7.3 with respect to amounts awarded by a court, arbitration panel or tribunal to a Third Party or with respect to claims of Fraud.

(e) Except in the case of Fraud and specific performance pursuant to Section 8.9, the right of the Incyte Indemnified Parties and the Prelude Indemnified Parties under this Article VII shall be the sole

and exclusive remedy of the Incyte Indemnified Parties and the Prelude Indemnified Parties, as the case may be, with respect to matters covered hereunder, including claims relating to the Products, the Transferred Assets, Excluded Assets, Assumed Liabilities or Excluded Liabilities.

(f) Incyte shall only be required to indemnify a Prelude Indemnified Party and Prelude shall only be required to indemnify an Incyte Indemnified Party for any particular claim one time.

(g) Each Indemnified Party shall use commercially reasonable efforts to mitigate its Losses upon and after becoming aware of any event or condition that would reasonably be expected to give rise to any Losses that are indemnifiable under this Agreement.

#### Section 7.5 Procedure.

(a) In order for any Prelude Indemnified Party or any Incyte Indemnified Party, as the case may be, under this Article VII (an “Indemnified Party”) to be entitled to any indemnification provided for under this Agreement, such Indemnified Party will, within 10 Business Days following the discovery of the matters giving rise to any Losses, notify the indemnifying party under this Article VII (the “Indemnifying Party”) in writing of its claim for indemnification for such Losses, specifying in reasonable detail the nature of such Losses and the amount of the liability estimated to accrue therefrom; provided, however, that failure to give such notification will not affect the indemnification provided hereunder, except to the extent the Indemnifying Party will have been actually prejudiced as a result of such failure. Except to preserve any attorney-client privilege, thereafter, the Indemnified Party will deliver to the Indemnifying Party, within 10 Business Days after the Indemnified Party’s receipt of such request, all information and documentation reasonably requested by the Indemnifying Party with respect to such Losses.

(b) If the indemnification sought pursuant hereto involves a claim made by a Third Party against the Indemnified Party (a “Third Party Claim”), the Indemnifying Party will be entitled to assume the defense of such Third Party Claim. Should the Indemnifying Party so elect to assume the defense of a Third Party Claim, the Indemnifying Party will not be liable to the Indemnified Party for any legal expenses subsequently incurred by the Indemnified Party in connection with the defense thereof. If the Indemnifying Party assumes such defense, the Indemnified Party will have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnifying Party, it being understood that the Indemnifying Party will control such defense. The Indemnifying Party will be liable for the reasonable fees and expenses of counsel employed by the Indemnified Party for any period during which the Indemnifying Party has not assumed the defense thereof. If the Indemnifying Party chooses to defend or prosecute a Third Party Claim, the Parties will cooperate in the defense or prosecution thereof. Such cooperation will include the retention and (upon the Indemnifying Party’s request) the provision to the Indemnifying Party of records and information which are reasonably relevant to such Third Party Claim, and making employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, it will defend or prosecute it diligently and the Indemnifying Party will obtain the prior written approval of the Indemnified Party (not to be unreasonably withheld) before entering into any settlement, compromise or discharge of such Third Party Claim if (i) pursuant to or as a result of such settlement, compromise or discharge, an injunction or other equitable relief may be imposed against the Indemnified Party, (ii) such settlement, compromise or discharge does not expressly unconditionally release the Indemnified Party from all Losses and liabilities with respect to such Third Party Claim and (iii) the Indemnifying Party is not directly paying the full amount of the Losses in connection with such Third Party Claim. Whether or not the Indemnifying Party will have assumed the defense of a Third Party Claim, the Indemnified Party will not admit any liability with respect to, or settle, compromise or discharge (or offer to do any of the foregoing with respect to), such Third Party Claim

without the Indemnifying Party's prior written consent (not to be unreasonably withheld or conditioned). The Parties will use their commercially reasonable efforts to minimize Losses from Third Party Claims and will act in good faith in responding to, defending against, settling or otherwise dealing with such claims.

Section 7.6 No Right of Set-Off. Notwithstanding anything else in this Agreement, Incyte shall not have any right to set off, in whole or in part, against any obligation or payment it owes to Prelude (including by deducting from or withholding any Contingent Payments that are or may become payable pursuant to this Agreement), amounts owed or claimed to be owed by Prelude to any Incyte Indemnified Party pursuant to this Agreement or any other Transaction Document.

Section 7.7 Tax. All payments made by an Indemnifying Party pursuant to this Article VII shall be treated as adjustments to the Consideration for Tax purposes.

## **ARTICLE VIII MISCELLANEOUS**

### Section 8.1 Confidentiality.

(a) The terms of the Confidentiality Agreements are hereby incorporated by reference, *mutatis mutandis*, and, notwithstanding anything contained in the Confidentiality Agreements to the contrary, shall continue in full force and effect until the Closing, at which time such Confidentiality Agreements and all obligations thereunder shall terminate.

(b) From and following the Closing, Prelude hereby agrees that Prelude will not, and will cause its Affiliates, stockholders, partners, members, directors, managers, officers, agents and Representatives not to, directly or indirectly, without the prior written consent of Incyte, disclose or use any Confidential Information with respect to the Transferred Assets or the Business; provided that the provisions of this Section 8.1 will not prohibit any (i) retention of copies of records or (ii) disclosure or use of any Confidential Information (A) required by applicable Law so long as, to the extent practicable, reasonable prior notice is given of such disclosure and a reasonable opportunity is afforded to contest the same or (B) made in connection with the enforcement of any right or remedy relating to this Agreement. Prelude agrees that it will be responsible for any breach or violation of the provisions of this Section 8.1 by any of its Affiliates, stockholders, partners, members, directors, managers, officers, agents or Representatives.

(c) For the avoidance of doubt, (x) all data or information of a confidential nature that relates to the Transferred Assets or the Business, as of the time of transfer to Incyte pursuant to the terms of this Agreement, and (y) all information provided to Prelude pursuant to Section 2.6, including any Net Sales Statements, shall be regarded as, and be solely relevant for the purposes of the definition of, "Confidential Information" of Incyte and its Affiliates.

(d) Except as required by judicial order or applicable Law, including the rules and regulations promulgated by the SEC or any other Governmental Authority, neither Party shall make any public announcement concerning, or otherwise disclose the terms of, this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. The Party preparing any such public announcement shall provide the other Party with a draft thereof at least 10 Business Days prior to the date on which such Party would like to make the public announcement.

Section 8.2 Assignment. This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective successors and permitted assigns. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party; provided, that, notwithstanding the foregoing, (a) either Party may, without consent of the other Party, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate of such Party, (b) Prelude may, without consent of Incyte, assign this Agreement and its rights and obligations hereunder in whole in a Change of Control transaction of Prelude, (c) Prelude may assign, sell, pledge, contribute or otherwise transfer, in whole or in part, its rights to any Contingent Payments hereunder and its rights to receive information from Incyte with respect to such Contingent Payments without the prior consent of Incyte, and (d) Incyte may, without consent of Prelude, assign this Agreement and its rights and obligations hereunder in whole or in part to the Third Party Transferee pursuant to Section 2.6(i); provided, further, that in the case of the foregoing clauses (a) to (d), the assigning Party provides written notice of such assignment to the non-assigning Party within 10 days after the effective date of such assignment; provided, further, that in the case of the foregoing clause (c), in no event shall a purchaser have any rights or remedies against Incyte with respect to the subject matter hereof and that any rights or remedies a purchaser may have with respect thereto shall be solely against Prelude. Any attempted assignment of this Agreement not in accordance with this Section 8.2 will be null, void, and of no legal effect. Any permitted assignee will assume all assigned obligations of its assignor under this Agreement. The terms and conditions of this Agreement will be binding upon, and will inure to the benefit of, the Parties and their respected successors and permitted assigns. Notwithstanding the foregoing, the assigning Party shall remain liable under this Agreement for the performance of all its obligations hereunder and shall be responsible and liable for compliance by its assignee Affiliate with the provisions of this Agreement.

Section 8.3 Amendment and Modification; Waiver. This Agreement may only be amended, modified or supplemented by an agreement in writing signed by each Party hereto. No waiver by any Party of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the Party so waiving. No waiver by any Party shall operate or be construed as a waiver in respect of any failure, breach or default not expressly identified by such written waiver, whether of a similar or different character, and whether occurring before or after that waiver. No failure to exercise, or delay in exercising, any right, remedy, power or privilege arising from this Agreement shall operate or be construed as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.

Section 8.4 Company Schedules. Prelude has or may have set forth information in the Company Schedules in a Section of such Company Schedules that corresponds to the Section of this Agreement to which it relates. The fact that any item of information is disclosed in any section or subsection of the Company Schedules shall be deemed disclosure with respect to any other section or subsection to which the relevance of such item is apparent based on a plain reading of such disclosure. Unless the context otherwise requires, all capitalized terms used in the Company Schedules shall have the respective meanings assigned to such terms in this Agreement. Certain information set forth in the Company Schedules is included solely for informational purposes and may not be required to be disclosed pursuant to this Agreement. No reference to or disclosure of any item or other matter in the Company Schedules shall be construed as an admission or indication that such item or other matter is required to be referred to or disclosed in the Company Schedules. No disclosure in the Company Schedules relating to any possible breach or violation of any agreement or Law shall be construed as an admission or indication that any such breach or violation exists or has actually occurred. The inclusion of any information in the Company Schedules shall not be deemed to be an admission or acknowledgment by Prelude that in and of itself, such information is material to or outside the ordinary course of the business or is required to be disclosed on

the Company Schedules. No disclosure in the Company Schedules shall be deemed to create any rights in any Third Party.

Section 8.5 Expenses. Except as otherwise expressly provided in this Agreement and the Transaction Documents, all costs and expenses, including fees and disbursements of counsel, financial advisors and accountants, incurred in connection with this Agreement and the transactions contemplated hereby shall be paid by the Party incurring such costs and expenses, whether or not the Closing shall have occurred.

Section 8.6 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Laws, and if the rights or obligations of either Party under this Agreement shall not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance here from, and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties herein.

Section 8.7 Governing Law. This Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, regardless of the Laws that might otherwise govern under applicable principles of conflicts of laws thereof.

Section 8.8 Dispute Resolution; Exclusive Jurisdiction and Venue.

(a) If any dispute, controversy, or claim arises out of or relates to this Agreement, including its existence, validity, breach, termination, or interpretation (a “Dispute”), either Party may deliver written notice describing the Dispute in reasonable detail. The Parties’ Executive Officers shall diligently and in good faith attempt to resolve the referred Dispute within 30 days after such notice (or such longer period as the Executive Officers may agree in writing). Any final decision mutually agreed to by the Executive Officers and set forth in writing shall be conclusive and binding on the Parties.

(b) If the Dispute is not resolved within 30 days after the notice under Section 8.8(a), such Dispute shall be settled by arbitration administered by the American Arbitration Association (“AAA”) under its Commercial Arbitration Rules (the “Rules”) and the procedures set forth in this Section 8.8. In the event of any inconsistency between the Rules and this Section 8.8, the provisions of this Section 8.8 shall control. The arbitration shall be conducted in Wilmington, Delaware, in the English language, by a panel of three neutral arbitrators who are independent and disinterested with respect to the Parties, this Agreement, and the outcome of the arbitration. Each Party shall appoint one neutral arbitrator, and those two arbitrators shall then select the third arbitrator, who shall serve as chair. All arbitrators must have at least 15 years’ experience in the biopharmaceutical industry and in mediating or arbitrating cases regarding the same or substantially similar subject matter as the Dispute. If one Party gives written notice of its appointed arbitrator and the other Party fails to appoint its arbitrator within 10 days after a written demand to do so, the arbitrator already appointed shall appoint the remaining two arbitrators. Either Party may seek emergency relief under the Rules (including the Optional Rules for Emergency Measures of Protection). The tribunal may grant interim or conservatory measures it deems appropriate, including specific performance and injunctive relief, and shall issue a reasoned award within nine months after its constitution, absent good cause. The arbitration and all related materials, submissions, evidence, and awards shall be treated as Confidential Information under this Agreement and disclosed only to the tribunal, the AAA, the

Parties and their Representatives with a need to know (subject to obligations of confidentiality), or as required by Law or to enforce, challenge, or defend the award. The fees of the arbitrators and costs and expenses of the arbitration shall be borne as allocated by the tribunal, which may award costs and fees, including AAA fees, arbitrator compensation, and reasonable attorneys' fees, to the prevailing Party as it deems appropriate. Judgment upon the award rendered by the tribunal may be entered in any court of competent jurisdiction.

(c) Nothing in this Section 8.8 limits either Party's right to seek temporary, preliminary, or injunctive relief or specific performance from the courts identified in Section 8.9 to preserve the status quo or prevent irreparable harm pending arbitration, or to confirm, enforce, correct, or vacate an arbitral award. Notwithstanding anything to the contrary in this Section 8.8, any Party may seek immediate injunctive or other interim relief from any court of competent jurisdiction as necessary to enforce the provisions in Section 8.1 and to enforce and prevent infringement or misappropriation of the Patent rights, Know-How or Confidential Information controlled by such Party.

Section 8.9 Specific Performance. The Parties agree that irreparable damage for which monetary damages, even if available, would not be an adequate remedy, would occur in the event that the Parties do not perform their obligations under the provisions of this Agreement in accordance with its specified terms or otherwise breach such provisions. The Parties acknowledge and agree that (a) the Parties shall be entitled to an injunction or injunctions, specific performance, or other equitable relief, to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof in the courts described in Section 8.8(a) without proof of monetary damages, this being in addition to any other remedy to which they are entitled under this Agreement, and (b) the right of specific performance is an integral part of the transactions contemplated hereby and without such right, neither Incyte nor Prelude would have entered into this Agreement. Each of the Parties agrees that it will not oppose the granting of an injunction, specific performance or other equitable relief on the basis that the other Party has an adequate remedy at Law. The Parties acknowledge and agree that any Party seeking an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in accordance with this Section 8.9 shall not be required to provide any bond or other security in connection with any such order or injunction. Notwithstanding the foregoing, to the fullest extent permitted under applicable Law, the Parties agree that in no event shall a Party be entitled, either in Law or equity, to rescind this Agreement and each Party waives the right to seek rescission of the Agreement.

Section 8.10 Notices. Any and all notices and communications under this Agreement shall be made in writing in the English language and delivered by hand, courier, telefax, or email to the Person at the address set forth below, or such other Person or address as may be designated by the respective Party to the other Party in the same manner:

if to Incyte:

Incyte Corporation  
1801 Augustine Cut-off  
Wilmington, DE 19803  
United States

Attn: [\*\*\*]  
Email: [\*\*\*]

with a copy to (which copy shall not constitute notice hereunder):

Sullivan & Cromwell LLP  
125 Broad Street  
New York, NY 10004  
United States

Attn.: Matthew Hurd, Rachel Yu and Mimi Wu  
Email: hurdm@sullcrom.com, yuru@sullcrom.com, wum@sullcrom.com

if to Prelude:

Prelude Therapeutics Incorporated  
175 Innovation Boulevard  
Wilmington, DE 19803

Attn.: Chief Legal Officer  
Email: legal@preludetx.com

with a copy to (which copy shall not constitute notice hereunder):  
Morgan Lewis & Bockius LLP  
2222 Market Street  
Philadelphia, PA 19103-3007

Attn.: Richard B. Aldridge and Andrew Haupt  
Email: richard.aldrige@morganlewis.com; andrew.haupt@morganlewis.com

Section 8.11 Entire Agreement. This Agreement contains the entire understanding, whether oral or written, of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, whether oral or written, heretofore made are expressly superseded by this Agreement.

Section 8.12 Further Assurances. The Parties shall, and shall cause their respective Affiliates to, promptly execute and deliver all documents, certificates, agreements and other writings and take all actions required to consummate, implement, effectuate, perfect, confirm or record the transactions contemplated by this Agreement.

Section 8.13 No Third-Party Beneficiaries. Except as expressly provided herein, this Agreement is for the sole benefit of the Parties hereto and their respective successors and permitted assigns and nothing herein, express or implied, is intended to or shall confer upon any other Person or entity any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

Section 8.14 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. If any signature is delivered by facsimile transmission or by e-mail delivery of a "PDF" format data file, such signature shall create a valid and binding obligation of the Party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or "PDF" signature page were an original thereof, provided that such facsimile or "PDF" signature is confirmed by an original signature.

*[Signature page follows]*

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized representatives as of the date first above written.

**PRELUDE THERAPEUTICS INCORPORATED**

By: \_\_\_\_\_  
Name:  
Title:

By: \_\_\_\_\_  
Name:  
Title:

**INCYTE CORPORATION**

By: \_\_\_\_\_  
Name:  
Title:

**Exhibit A**  
**Assignment and Assumption and Bill of Sale Agreement**

This exhibit has been omitted pursuant to Item 601(a)(5).

4931-5190-9491 v.7

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**Exhibit B**  
**Patent Assignment Agreement**

This exhibit has been omitted pursuant to Item 601(a)(5).

4931-5190-9491 v.7

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**Exhibit C**  
**Assay of V617F Mutative Selective Inhibitors**

This exhibit has been omitted pursuant to Item 601(a)(5).

4931-5190-9491 v.7

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**EXHIBIT B**  
**DATA SETS FOR IND READY DATA PACKAGE**

This exhibit has been omitted pursuant to Item 601(a)(5).

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**EXHIBIT C**  
**ASSAY USED TO MEASURE IC50 FOR**  
**V617F MUTATIVE SELECTIVE INHIBITORS**

This exhibit has been omitted pursuant to Item 601(a)(5).

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**EXHIBIT D**  
**TARGET CANDIDATE PROFILE**

This exhibit has been omitted pursuant to Item 601(a)(5).

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**EXHIBIT E**  
**ABSTRACTS AND PRESENTATIONS**

**Discovery and preclinical characterization of orally bioavailable JAK2V617F mutant selective JH2 inhibitors with disease modification potential in myeloproliferative neoplasms**

*Neha Bhagwat, Duanya Liu, Xiaowei Wu, Alexander Grego, Amy Crossan, Andrew Moore, Arpita Mondal, Carly Bachner, Dani Roth, Diego Elrio, John Rose, Joseph Rager, Joy Cote, Kirsten Gallagher, Klare Bersch, Miles Cowart, Min Wang, Natalie Kurtz, Norman Fultang, Sharayu Chandratre, Song Mei, Srijita Dhar, Sushanta Ratna, Stephanie Rodgers, Yann Loret, Yue Zou, Sandy Geeganage, Andrew Combs, Jean-Jacques Kiladjian, Stephane Giraudier, Peggy Scherle*

The *JAK2V617F* mutation is the most common genetic alteration in patients with myeloproliferative neoplasms (MPNs), present in >90% of patients with polycythemia vera (PV) and 50-60% of patients with essential thrombocythemia (ET) and myelofibrosis (MF). This mutation results in constitutive and growth factor-independent activation of the JAK-STAT signaling pathway, leading to hyperproliferation and myelofibrosis.

Current therapies for MPNs, such as first-generation JAK inhibitors like ruxolitinib, target the JH1 kinase domain and inhibit both wildtype (WT) and mutant JAK2V617F (JAK2VF) with equal potency. As such, their efficacy is limited by dose-limiting cytopenias due to WT JAK2 inhibition in normal hematopoietic tissue and insufficient inhibition of mutant JAK2 needed to alter disease course. Next-generation JAK2VF selective inhibitors could achieve deeper inhibition of mutant JAK2 while sparing WT, offering the potential for improved clinical and molecular responses with disease-modifying effects.

Our medicinal chemistry strategy focused on targeting the JAK2 pseudokinase (JH2) binding site wherein the V617F mutation resides. Utilizing structure-based drug design, we created *de novo* a series of highly potent, allosteric JAK2VF selective inhibitors that bind into the deep pocket containing the Phe-triad formed by the V617F residue along with F594 and F595. X-ray co-crystal structures of JAK2VF with multiple lead compounds confirmed our distinct “deep pocket” binding mode compared to previously reported JH2 inhibitors. These lead JAK2VF selective inhibitors exhibited >100-fold selectivity over other JAK family isoforms (JAK1, JAK3 and TYK2 JH2 domains) and were highly selective against >300 kinases, including the JAK2 JH1 domain.

In cellular phosphoproteomic assays, these molecules selectively inhibited phosphorylation of downstream proteins, including STATs, MAPK and AKT, in JAK2VF cells compared to WT cells. In addition, these compounds showed potent and dose dependent anti-proliferative activity in JAK2VF cell lines and primary patient CD34+ cells in *ex vivo* cultures (IC<sub>50</sub> 50-100 nM) compared to WT cells (IC<sub>50</sub>>1μM). Treatment of JAK2VF patient CD34+ cells with the mutant selective inhibitors resulted in a selective reduction of JAK2VF variant allele frequency (VAF).

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Mechanistically, treatment with these compounds induced G1/S cell cycle arrest and apoptosis selectively in JAK2VF cell lines, with minimal effects in WT cells.

*In vivo*, oral administration of the JAK2VF selective inhibitors resulted in potent and selective inhibition of pSTAT5 in JAK2VF tumor tissue (>90%), with minimal inhibition observed in EPO-induced pSTAT5 signaling in JAK2 WT spleen (<25%) in the SET2 xenograft model. Significant dose-dependent tumor growth inhibition (>70%), similar to ruxolitinib, was observed at well-tolerated doses in this model. In the BaF3-EPOR-JAK2VF model, treatment normalized splenomegaly (>70% decrease in spleen size) and reduced inflammatory cytokines.

The JAK2 VF selective inhibitors were also evaluated in a head-to-head study with ruxolitinib in the JAK2VF bone marrow transplant mouse model (Marty et al. Blood 2010). Inhibitor treatment outperformed ruxolitinib in all clinicohematological parameters, leading to normalization of white blood cells, platelets and spleen size without causing cytopenias or other adverse effects. Importantly, there was a significant reduction in hematocrit and hemoglobin, which was not achieved with ruxolitinib and is consistent with published reports. Multiple inflammatory cytokines were also suppressed with inhibitor treatment, similar to ruxolitinib. Most importantly, analysis of stem and progenitor populations revealed *a selective decrease* in proliferation of JAK2VF long-term HSCs as well as megakaryocyte-erythroid progenitor populations, key contributors to MPN pathogenesis, without an impact on WT cells, in contrast to ruxolitinib which has similar effects on both JAK2VF and WT cells.

These data establish our JAK2VF selective inhibitors as potential first-in-class agents with disease-modifying potential. They achieve deep molecular engagement via Phe-triad targeting, demonstrate exceptional selectivity, and show *in vivo* efficacy superior to ruxolitinib. This approach holds promise for transforming the treatment landscape in MPNs by directly targeting the molecular cause of disease. Prelude is now advancing a development candidate into Phase 1 clinical studies.

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**SCHEDULE 1.59**  
**V617F Patents**

This exhibit has been omitted pursuant to Item 601(a)(5).

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**REGISTRATION RIGHTS AGREEMENT**

This Registration Rights Agreement (this “Agreement”) is made as of November 10, 2025, by and between Prelude Therapeutics Incorporated, a Delaware corporation (the “Company”), and Incyte Corporation (the “Investor”). Unless otherwise defined herein, capitalized terms used in this Agreement have the respective meanings ascribed to them in Section 1.

**RECITALS**

**WHEREAS**, the Company and the Investor are entering into a Securities Purchase Agreement, dated as of the date hereof (the “Securities Purchase Agreement”), pursuant to which the Company will issue and sell to the Investor shares (the “Shares”) of the Company’s non-voting Common Stock, par value \$0.0001 per share (the “Non-Voting Common Stock”).

**WHEREAS**, execution and delivery of this Agreement are conditions to closing for the Company and the Investor under the Securities Purchase Agreement.

**NOW, THEREFORE**, in consideration of the mutual promises and covenants set forth herein, and other consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereto agree as follows:

**Definitions**

Certain Definitions. In addition to the terms defined elsewhere in this Agreement, as used in this Agreement, the following terms have the respective meanings set forth below:

“Board” shall mean the Board of Directors of the Company.

“Commission” shall mean the Securities and Exchange Commission or any other federal agency at the time administering the Securities Act.

“Common Stock” shall mean the voting and non-voting common stock of the Company, par value \$0.0001 per share.

“Exchange Act” shall mean the Securities Exchange Act of 1934, as amended, or any similar successor federal statute and the rules and regulations thereunder, all as the same shall be in effect from time to time.

“Other Securities” shall mean securities of the Company, other than Registrable Securities.

“Person” shall mean any individual, partnership, corporation, company, association, trust, joint venture, limited liability company, unincorporated organization, entity or division, or any government, governmental department or agency or political subdivision thereof.

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“Registrable Securities” shall mean the Shares acquired by the Investor pursuant to the Securities Purchase Agreement. Registrable Securities held by the Investor shall cease to be Registrable Securities upon the earliest to occur of the following events: (i) such Registrable Securities have been sold pursuant to an effective Registration Statement; (ii) such Registrable Securities have been sold by the Investor pursuant to Rule 144 (or other similar rule), (iii) such Registrable Securities may be resold by the Investor holding such Registrable Securities without limitations as to volume or manner of sale pursuant to Rule 144; or (iv) five (5) years after the date of this Agreement. For purposes of this definition, in order to determine whether an Investor is an “affiliate” (as such term is defined and used in Rule 144, and including for determining whether volume or manner of sale limitations of Rule 144 apply) the parties will assume that all convertible securities (whether equity, debt or otherwise) have been converted into Common Stock without regard to any limitations on conversion applicable thereto.

The terms “register,” “registered” and “registration” shall refer to a registration effected by preparing and filing a Registration Statement in compliance with the Securities Act, and such Registration Statement becoming effective under the Securities Act.

“Registration Expenses” shall mean all expenses incurred by the Company in effecting any registration pursuant to this Agreement, including, without limitation, all registration, qualification, and filing fees, printing expenses, escrow fees, fees and disbursements of counsel for the Company, blue sky fees and expenses, and expenses of any regular or special audits incident to or required by any such registration, but shall not include Selling Expenses.

“Registration Statement” means any registration statement of the Company filed with, or to be filed with, the Commission under the Securities Act, including the related prospectus, amendments and supplements to such registration statement, including pre- and post-effective amendments, and all exhibits and all material incorporated by reference in such registration statement as may be necessary to comply with applicable securities laws other than a registration statement (and related prospectus) filed on Form S-4 or Form S-8 or any successor forms thereto.

“Rule 144” shall mean Rule 144 as promulgated by the Commission under the Securities Act, as such rule may be amended from time to time, or any similar successor rule that may be promulgated by the Commission.

“Securities Act” shall mean the Securities Act of 1933, as amended, or any similar successor federal statute and the rules and regulations thereunder, all as the same shall be in effect from time to time.

“Selling Expenses” shall mean all underwriting discounts and selling commissions applicable to the sale of Registrable Securities, the fees and expenses of any legal counsel and any other advisors the Investor engages and all similar fees and commissions relating to the Investor’s disposition of the Registrable Securities.

## **Resale Registration Rights**

### Resale Registration Rights.

Following demand by the Investor, the Company shall file with the Commission a Registration Statement on Form S-3 (except if the Company is not then eligible to register for resale the Registrable Securities on Form S-3, in which case such registration shall be on another appropriate form in accordance with the Securities Act) covering the resale of the Registrable Securities by the Investor (the “Resale Registration Shelf”), and the Company shall file such Resale Registration Shelf as promptly as reasonably practicable following such demand, and in any event within sixty (60) days of such demand. Such Resale Registration Shelf shall include a “final” prospectus, including the information required by Item 507 of Regulation S-K of the Securities Act, as provided by the Investor in accordance with Section 2.7. Notwithstanding the foregoing, before filing the Resale Registration Shelf, the Company shall furnish to the Investor a copy of the Resale Registration Shelf and afford the Investor an opportunity to review and comment on the Resale Registration Shelf. The Company’s obligation pursuant to this Section 2.1(a) is conditioned upon the Investor providing the information contemplated in Section 2.7.

Promptly following the Closing Date (as defined in the Securities Purchase Agreement) but no later than thirty (30) days after the Closing Date, the Company shall prepare and file with the Commission a Registration Statement on Form S-3 (except if the Company is not then eligible to register for resale the Registrable Securities on Form S-3, in which case such registration shall be on another appropriate form in accordance with the Securities Act) covering the resale of all of the Shares (“Shares Shelf Registration Statement”). Such Shares Shelf Registration Statement shall include a “final” prospectus, including the information required by Item 507 of Regulation S-K of the Securities Act, as provided by the Investor in accordance with Section 2.7. Notwithstanding the foregoing, before filing the Shares Shelf Registration Statement, the Company shall furnish to the Investor a copy of the Shares Shelf Registration Statement and afford the Investor a reasonable opportunity to review and comment on the Shares Shelf Registration Statement. The Company’s obligation pursuant to this Section 2.1(b) is conditioned upon the Investor providing the information contemplated in Section 2.7.

The Company shall use its reasonable best efforts to cause the Resale Registration Shelf, the Shares Shelf Registration Statement and related prospectuses, as applicable, to become effective as promptly as practicable after filing. The Company shall use its reasonable best efforts to cause such Registration Statements to remain effective under the Securities Act until the earlier of the date (i) all Registrable Securities covered by the Resale Registration Shelf and the Shares Shelf Registration Statement, as applicable, have been sold or (ii) all Registrable Securities covered by the Resale Registration Shelf and the Shares Shelf Registration Statement, as applicable, otherwise cease to be Registrable Securities. The Company shall promptly, and within two (2) business days after the Company confirms effectiveness of the Resale Registration Shelf or the Shares Shelf Registration Statement, as applicable, with the Commission, notify the Investor of the

effectiveness of the Resale Registration Shelf or the Shares Shelf Registration Statement, as applicable.

Notwithstanding anything contained herein to the contrary, the Company shall not be obligated to effect, or to take any action to effect, a registration pursuant to Section 2.1(a) or Section 2.1(b):

if the Company has and maintains an effective Registration Statement on Form S-3ASR that provides for the resale of an unlimited number of securities by selling stockholders (a “Company Registration Shelf”);

during the period forty-five (45) days prior to the Company’s good faith estimate of the date of filing of a Company Registration Shelf; or

if the Company has caused a Registration Statement to become effective pursuant to this Section 2.1 during the prior twelve (12) month period.

If the Company has a Company Registration Shelf in place at any time in which the Investor makes a demand pursuant to Section 2.1(a), the Company shall file with the Commission, as promptly as practicable, and in any event within fifteen (15) business days after such demand, a “final” prospectus supplement to its Company Registration Shelf covering the resale of the Registrable Securities by the Investor (the “Prospectus”); provided, however, that the Company shall not be obligated to file more than one Prospectus pursuant to this Section 2.1(e) in any six month period to add additional Registrable Securities to the Company Registration Shelf that were acquired by the Investor other than directly from the Company or in an underwritten public offering by the Company. The Prospectus shall include the information required under Item 507 of Regulation S-K of the Securities Act, which information shall be provided by the Investor in accordance with Section 2.7. Notwithstanding the foregoing, before filing the Prospectus, the Company shall furnish to the Investor a copy of the Prospectus and afford the Investor an opportunity to review and comment on the Prospectus.

Deferral and Suspension. At any time after being obligated to file a Resale Registration Shelf, the Shares Shelf Registration Statement or Prospectus, or after any Resale Registration Shelf or Shares Shelf Registration Statement has become effective or a Prospectus is filed with the Commission (in each case, including pursuant to an Other RRA), the Company may defer the filing of or suspend the use of any such Resale Registration Shelf, Shares Shelf Registration Statement or Prospectus, upon giving written notice of such action to the Investor with a certificate signed by the Principal Executive Officer of the Company stating that in the good faith judgment of the Board, the filing or use of any such Resale Registration Shelf, Shares Shelf Registration Statement or Prospectus covering the Registrable Securities would be seriously detrimental to the Company or its stockholders at such time and that the Board concludes, as a result, that it is in the best interests of the Company and its stockholders to defer the filing or suspend the use of such Resale Registration Shelf, Shares Shelf Registration Statement or Prospectus at such time. The Company shall have the right to defer the filing of or suspend the use of such Resale Registration Shelf, Shares Shelf Registration Statement or

Prospectus for a period of not more than one hundred twenty (120) days from the date the Company notifies the Investor of such deferral or suspension; provided that the Company shall not exercise the right contained in this Section 2.1(f) more than once in any twelve month period. In the case of the suspension of use of any effective Resale Registration Shelf, Shares Shelf Registration Statement or Prospectus, the Investor, immediately upon receipt of notice thereof from the Company, shall discontinue any offers or sales of Registrable Securities pursuant to such Resale Registration Shelf, Shares Shelf Registration Statement or Prospectus until advised in writing by the Company that the use of such Resale Registration Shelf, Shares Shelf Registration Statement or Prospectus may be resumed. In the case of a deferred Prospectus or Resale Registration Shelf filing or Shares Shelf Registration Statement, the Company shall provide prompt written notice to the Investor of (i) the Company's decision to file or seek effectiveness of the Prospectus or Resale Registration Shelf or Shares Shelf Registration Statement, as the case may be, following such deferral and (ii) in the case of a Resale Registration Shelf or Shares Shelf Registration Statement, the effectiveness of such Resale Registration Shelf or Shares Shelf Registration Statement. In the case of either a suspension of use of, or deferred filing of, any Resale Registration Shelf, Shares Shelf Registration Statement or Prospectus, the Company shall not, during the pendency of such suspension or deferral, be required to take any action hereunder (including any action pursuant to Section 2.2 hereof) with respect to the registration or sale of any Registrable Securities pursuant to any such Resale Registration Shelf, Shares Shelf Registration Statement, Company Registration Shelf or Prospectus.

Other Securities. Any Resale Registration Shelf, Shelf Registration Statement or Prospectus may include Other Securities, and may include securities of the Company being sold for the account of the Company; provided such Other Securities are excluded first from such Registration Statement in order to comply with any applicable laws or request from the Commission, Nasdaq or any applicable listing agency. For the avoidance of doubt, no Other Securities may be included in an underwritten offering pursuant to Section 2.2 without the consent of the Investor except as expressly set forth herein.

#### Sales and Underwritten Offerings of the Registrable Securities.

Notwithstanding any provision contained herein to the contrary, the Investor shall and, subject to the limitations set forth in this Section 2.2, be entitled to demand up to two underwritten public offerings to effect the sale or distribution of Registrable Securities during the term of this Agreement.

If the Investor intends to effect an underwritten public offering pursuant to a Resale Registration Shelf, Shares Shelf Registration Statement or Company Registration Shelf to sell or otherwise distribute Registrable Securities, they shall so advise the Company and provide as much notice to the Company as reasonably practicable (and in any event not less than fifteen (15) business days prior to the Investor's request that the Company file a prospectus supplement to a Resale Registration Shelf, Shares Shelf Registration Statement or Company Registration Shelf).

In connection with any offering initiated by the Investor pursuant to this Section 2.2 involving an underwriting of shares of Registrable Securities, the Investor shall be entitled to select the underwriter or underwriters for such offering, subject to the consent of the Company, such consent not to be unreasonably withheld, conditioned or delayed.

In connection with any offering initiated by the Investor pursuant to this Section 2.2 involving an underwriting of shares of Registrable Securities, the Company shall not be required to include any of the Registrable Securities in such underwriting unless the Investor (i) enters into an underwriting agreement in customary form with the underwriter or underwriters, (ii) accepts customary terms in such underwriting agreement with regard to representations and warranties relating to ownership of the Registrable Securities and authority and power to enter into such underwriting agreement and (iii) completes and executes all questionnaires, powers of attorney, custody agreements, indemnities and other documents as may be requested by such underwriter or underwriters. Further, the Company shall not be required to include any of the Registrable Securities in such underwriting if (Y) the underwriting agreement proposed by the underwriter or underwriters contains representations, warranties or conditions that are not reasonable in light of the Company's then-current business or (Z) the underwriter, underwriters or the Investor require the Company to participate in any marketing, road show or comparable activity that may be required to complete the orderly sale of shares by the underwriter or underwriters.

If the total amount of securities to be sold in any underwritten public offering initiated by the Investor pursuant to this Section 2.2 exceeds the amount that the underwriters determine in their sole discretion is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities (subject in each case to the cutback provisions set forth in this Section 2.2(e)), that the underwriters and the Company determine in their sole discretion shall not jeopardize the success of the offering. If the underwritten public offering has been requested pursuant to Section 2.2(a) of this Agreement, the number of shares that are entitled to be included in the registration and underwriting shall be allocated in the following manner: (a) first, shares of Company equity securities that the Company desires to include in such registration shall be excluded and (b) second, Registrable Securities requested to be included in such registration by the Investor shall be excluded, *pro rata*.

Fees and Expenses. All Registration Expenses incurred in connection with registrations pursuant to this Agreement shall be borne by the Company. All Selling Expenses relating to securities registered on behalf of the Investor shall be borne by the Investor.

Registration Procedures. In the case of each registration of Registrable Securities effected by the Company pursuant to Section 2.1 hereof (including, for the avoidance of doubt, Section 2.1(g)), the Company shall keep the Investor advised as to the initiation of each such registration and as to the status thereof. The Company shall use its reasonable best efforts, within the limits set forth in this Section 2.4, to:

prepare and file with the Commission such amendments and supplements to such Registration Statement and the prospectuses used in connection with such Registration Statement as may be necessary to keep such Registration Statement effective and current and comply with the provisions of the Securities Act with respect to the disposition of all securities covered by such Registration Statement;

furnish to the Investor such numbers of copies of a prospectus, including preliminary prospectuses, in conformity with the requirements of the Securities Act, and such other documents as the Investor may reasonably request in order to facilitate the disposition of Registrable Securities;

use its reasonable best efforts to register and qualify the Registrable Securities covered by such Registration Statement under such other securities or blue sky laws of such jurisdictions in the United States as shall be reasonably requested by the Investor, provided that the Company shall not be required in connection therewith or as a condition thereto to qualify to do business or to file a general consent to service of process in any such states or jurisdictions;

in the event of any underwritten public offering, and subject to Section 2.2(d), enter into and perform its obligations under an underwriting agreement, in usual and customary form (including any “lock-ups” on behalf of the Company and its directors and officers), with the managing underwriter of such offering and take such other usual and customary action as the Investor may reasonably request in order to facilitate the disposition of such Registrable Securities;

notify the Investor at any time when a prospectus relating to a Registration Statement covering any Registrable Securities is required to be delivered under the Securities Act of the happening of any event as a result of which the prospectus included in such Registration Statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing. The Company shall use its reasonable best efforts to amend or supplement such prospectus in order to cause such prospectus not to include any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing;

provide a transfer agent and registrar for all Registrable Securities registered pursuant to such Registration Statement and, if required, a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

if requested by an Investor, use reasonable best efforts to cause the Company’s transfer agent to remove any restrictive legend from any Registrable Securities, within two business days following such request;

cause to be furnished, at the request of the Investor, on the date that Registrable Securities are delivered to underwriters for sale in connection with an underwritten offering pursuant to this Agreement, (i) an opinion, dated such date, of the counsel representing the

Company for the purposes of such registration, in form and substance as is customarily given to underwriters in an underwritten public offering, addressed to the underwriters, and (ii) a letter or letters from the independent certified public accountants of the Company, in form and substance as is customarily given by independent certified public accountants to underwriters in an underwritten public offering, addressed to the underwriters; and

cause all such Registrable Securities included in a Registration Statement pursuant to this Agreement to be listed on each securities exchange or other securities trading markets on which Common Stock is then listed.

#### The Investor's Obligations.

Discontinuance of Distribution. The Investor agrees that, upon receipt of any notice from the Company of the occurrence of any event of the kind described in Section 2.4(e) hereof, the Investor shall immediately discontinue disposition of Registrable Securities pursuant to any Registration Statement covering such Registrable Securities until the Investor's receipt of the copies of the supplemented or amended prospectus contemplated by Section 2.4(e) hereof or receipt of notice that no supplement or amendment is required and that the Investor's disposition of the Registrable Securities may be resumed. The Company may provide appropriate stop orders to enforce the provisions of this Section 2.5(a).

Compliance with Prospectus Delivery Requirements. The Investor covenants and agrees that it shall comply with the prospectus delivery requirements of the Securities Act as applicable to them or an exemption therefrom in connection with sales of Registrable Securities pursuant to any Registration Statement filed by the Company pursuant to this Agreement.

Notification of Sale of Registrable Securities. The Investor covenants and agrees that it shall notify the Company following the sale of Registrable Securities to a third party as promptly as reasonably practicable, and in any event within thirty (30) days, following the sale of such Registrable Securities.

#### Indemnification.

To the extent permitted by law, the Company shall indemnify the Investor, and, as applicable, their officers, directors, and constituent partners, legal counsel for each Investor and each Person controlling the Investor, with respect to which registration, related qualification, or related compliance of Registrable Securities has been effected pursuant to this Agreement, and each underwriter, if any, and each Person who controls any underwriter within the meaning of the Securities Act against all claims, losses, damages, or liabilities (or actions in respect thereof) to the extent such claims, losses, damages, or liabilities arise out of or are based upon (i) any untrue statement (or alleged untrue statement) of a material fact contained in any prospectus or other document (including any related Registration Statement) incident to any such registration, qualification, or compliance, or (ii) any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, or

(iii) any violation or alleged violation by the Company of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities law applicable to the Company and relating to action or inaction required of the Company in connection with any such registration, qualification, or compliance; and the Company shall pay as incurred to the Investor, each such underwriter, and each Person who controls the Investor or underwriter, any legal and any other expenses reasonably incurred in connection with investigating or defending any such claim, loss, damage, liability, or action; provided, however, that the indemnity contained in this Section 2.6(a) shall not apply to amounts paid in settlement of any such claim, loss, damage, liability, or action if settlement is effected without the consent of the Company (which consent shall not unreasonably be withheld); and provided, further, that the Company shall not be liable in any such case to the extent that any such claim, loss, damage, liability, or expense arises out of or is based upon any violation by such Investor of the obligations set forth in Section 2.5 hereof or any untrue statement or omission contained in such prospectus or other document based upon written information furnished to the Company by the Investor, such underwriter, or such controlling Person and stated to be for use therein.

To the extent permitted by law, each Investor (severally and not jointly) shall, if Registrable Securities held by such Investor are included for sale in the registration and related qualification and compliance effected pursuant to this Agreement, indemnify the Company, each of its directors, each officer of the Company who signs the applicable Registration Statement, each legal counsel and each underwriter of the Company's securities covered by such a Registration Statement, each Person who controls the Company or such underwriter within the meaning of the Securities Act against all claims, losses, damages, and liabilities (or actions in respect thereof) arising out of or based upon (i) any untrue statement (or alleged untrue statement) of a material fact contained in any such Registration Statement, or related document, or (ii) any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, or (iii) any violation or alleged violation by such Investor of Section 2.5 hereof, the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities law applicable to such Investor and relating to action or inaction required of such Investor in connection with any such registration and related qualification and compliance, and shall pay as incurred to such persons, any legal and any other expenses reasonably incurred in connection with investigating or defending any such claim, loss, damage, liability, or action, in each case only to the extent that such untrue statement (or alleged untrue statement) or omission (or alleged omission) is made in (and such violation pertains to) such Registration Statement or related document in reliance upon and in conformity with written information furnished to the Company by such Investor and stated to be specifically for use therein; provided, however, that the indemnity contained in this Section 2.6(b) shall not apply to amounts paid in settlement of any such claim, loss, damage, liability, or action if settlement is effected without the consent of such Investor (which consent shall not unreasonably be withheld); provided, further, that such Investor's liability under this Section 2.6(b) (when combined with any amounts such Investor is liable for under Section 2.6(d)) shall not exceed such Investor's net proceeds from the offering of securities made in connection with such registration.

Promptly after receipt by an indemnified party under this Section 2.6 of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against an indemnifying party under this Section 2.6, notify the indemnifying party in writing of the commencement thereof and generally summarize such action. The indemnifying party shall have the right to participate in and to assume the defense of such claim; provided, however, that the indemnifying party shall be entitled to select counsel for the defense of such claim with the approval of any parties entitled to indemnification, which approval shall not be unreasonably withheld; provided further, however, that if either party reasonably determines that there may be a conflict between the position of the Company and the Investor in conducting the defense of such action, suit, or proceeding by reason of recognized claims for indemnity under this Section 2.6, then counsel for such party shall be entitled to conduct the defense to the extent reasonably determined by such counsel to be necessary to protect the interest of such party. The failure to notify an indemnifying party promptly of the commencement of any such action, if prejudicial to the ability of the indemnifying party to defend such action, shall relieve such indemnifying party, to the extent so prejudiced, of any liability to the indemnified party under this Section 2.6, but the omission so to notify the indemnifying party shall not relieve such party of any liability that such party may have to any indemnified party otherwise than under this Section 2.6.

If the indemnification provided for in this Section 2.6 is held by a court of competent jurisdiction to be unavailable to an indemnified party with respect to any loss, liability, claim, damage, or expense referred to therein, then the indemnifying party, in lieu of indemnifying such indemnified party hereunder, shall contribute to the amount paid or payable by such indemnified party as a result of such loss, liability, claim, damage, or expense in such proportion as is appropriate to reflect the relative fault of the indemnifying party on the one hand and of the indemnified party on the other in connection with the statements or omissions that resulted in such loss, liability, claim, damage, or expense as well as any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission. In no event, however, shall (i) any amount due for contribution hereunder be in excess of the amount that would otherwise be due under Section 2.6(a) or Section 2.6(b), as applicable, based on the limitations of such provisions and (ii) a Person guilty of fraudulent misrepresentation (within the meaning of the Securities Act) be entitled to contribution from a Person who was not guilty of such fraudulent misrepresentation.

Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with an underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control; provided, however, that the failure of the underwriting agreement to provide for or address a matter provided for or addressed by the foregoing provisions shall not be a conflict between the underwriting agreement and the foregoing provisions.

The obligations of the Company and the Investor under this Section 2.6 shall survive the completion of any offering of Registrable Securities in a Registration Statement under this Agreement or otherwise.

Information. The Investor shall furnish to the Company such information regarding the Investor and the distribution proposed by the Investor as the Company may reasonably request and as shall be reasonably required in connection with any registration referred to in this Agreement. The Investor agrees to, as promptly as practicable (and in any event prior to any sales made pursuant to a prospectus), furnish to the Company all information required to be disclosed in order to make the information previously furnished to the Company by the Investor not misleading. The Investor agrees to keep confidential the receipt of any notice received pursuant to Section 2.4(e) and the contents thereof, except as required pursuant to applicable law. Notwithstanding anything to the contrary herein, the Company shall be under no obligation to name the Investor in any Registration Statement if the Investor has not provided the information required by this Section 2.7 with respect to the Investor as a selling securityholder in such Registration Statement or any related prospectus.

Rule 144 Requirements. With a view to making available to the Investor the benefits of Rule 144 and any other rule or regulation of the Commission that may at any time permit the Investor to sell Registrable Securities to the public without registration, the Company agrees to use its reasonable best efforts to:

make and keep public information available, as those terms are understood and defined in Rule 144 at all times after the date hereof;

file with the Commission in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act;

prior to the filing of a Registration Statement or any amendment thereto (whether pre-effective or post-effective), and prior to the filing of any prospectus or prospectus supplement related thereto, to provide the Investor with copies of all of the pages thereof (if any) that reference the Investor; and

furnish to the Investor, so long as the Investor owns any Registrable Securities, forthwith upon request (i) a written statement by the Company that it has complied with the reporting requirements of Rule 144, (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company, and (iii) such other information as may be reasonably requested by an Investor in availing itself of any rule or regulation of the Commission which permits an Investor to sell any such securities without registration.

Limitations on Subsequent Registration Rights. From and after the date of this Agreement, the Company shall not, without prior written consent of the Investor, (a) enter into any agreement with any holder or prospective holder of any securities of the Company that would provide to such holder rights with respect to the registration of such securities under the Securities Act or the Exchange Act that would conflict with or adversely affect any of the rights provided to the Investor in this Section 2, (and, in the case of any such amendment, the Company shall notify the Investor

in advance of such amendment for it to determine whether such amendment would conflict with or adversely affects their rights in this Section 2); it being understood and agreed that any subsequent agreement of the Company with any holder or prospective holder of any securities of the Company of the same class (or convertible into or exchange for securities of the same class) as the Registrable Securities that grants rights equivalent to the rights of the Investor under this Section 2 will not be prohibited by the terms of this Section 2.9 so long as the inclusion of such holder or prospective holder's securities will not reduce the number of the Registrable Securities of the Holders that are included in any registration hereunder or thereunder.

### **Miscellaneous**

Amendment. No amendment, alteration or modification of any of the provisions of this Agreement shall be binding unless made in writing and signed by each of the Company and the Investor.

Injunctive Relief. It is hereby agreed and acknowledged that it shall be impossible to measure in money the damages that would be suffered if the parties fail to comply with any of the obligations herein imposed on them and that in the event of any such failure, an aggrieved Person shall be irreparably damaged and shall not have an adequate remedy at law. Any such Person shall, therefore, be entitled (in addition to any other remedy to which it may be entitled in law or in equity) to injunctive relief, including, without limitation, specific performance, to enforce such obligations, and if any action should be brought in equity to enforce any of the provisions of this Agreement, none of the parties hereto shall raise the defense that there is an adequate remedy at law.

Notices. All notices required or permitted under this Agreement must be in writing and sent to the address or facsimile number identified below. Notices must be given: (a) by personal delivery, with receipt acknowledged; (b) by email followed by hard copy delivered by the methods under clause (c) or (d); (c) by prepaid certified or registered mail, return receipt requested; or (d) by prepaid reputable overnight delivery service. Notices shall be effective upon receipt. Either party may change its notice address by providing the other party written notice of such change. Notices shall be delivered as follows:

If to the Investor:

Incyte Corporation  
1801 Augustine Cut-off  
Wilmington, DE 19803  
Attn: Sheila Denton  
Email: [sdenton@incyte.com](mailto:sdenton@incyte.com)

With a copy (which will not constitute notice) to:

Sullivan & Cromwell LLP  
125 Broad Street  
New York, NY 11211  
Attention: Matt Hurd, Rachel Yu and Mimi Wu

E-mail: hurdm@sullcrom.com, yuru@sullcrom.com, wum@sullcrom.com

If to the Company:

175 Innovation Boulevard  
Wilmington, DE 19805  
Attention: Chief Legal Officer  
Email: legal@preludetx.com

with a copy to:

Morgan, Lewis Bockius LLP  
2222 Market Street  
Philadelphia, PA 19103  
Attention: Richard Aldridge  
E-mail: richard.aldrige@morganlewis.com

Governing Law; Jurisdiction; Venue; Jury Trial.

This Agreement shall be governed by, and construed in accordance with, the law of the State of New York without giving effect to any choice or conflict of law provision or rule (whether of the State of New York or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New York.

Each of the Company and the Investor irrevocably and unconditionally submits, for itself and its property, to the nonexclusive jurisdiction of the courts of the State of New York sitting in the Borough of Manhattan, New York and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, in any action or proceeding arising out of or relating to this Agreement and the transactions contemplated herein, or for recognition or enforcement of any judgment, and each of the Company and the Investor irrevocably and unconditionally agrees that all claims in respect of any such action or proceeding may be heard and determined in such New York state court or, to the fullest extent permitted by applicable law, in such federal court. Each of the Company and the Investor hereto agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

Each of the Company and the Investor irrevocably and unconditionally waives, to the fullest extent permitted by applicable law, any objection that it may now or hereafter have to the laying of venue of any action or proceeding arising out of or relating to this Agreement and the transactions contemplated herein in any court referred to in Section 3.4(b) hereof. Each of the Company and the Investor hereby irrevocably waives, to the fullest extent permitted by applicable law, the defense of an inconvenient forum to the maintenance of such action or proceeding in any such court.

EACH OF THE COMPANY AND THE INVESTOR HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING

DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH OF THE COMPANY AND THE INVESTOR (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PERSON HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PERSON WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT EACH OF THE COMPANY AND THE INVESTOR HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION.

Successors, Assigns and Transferees. Any and all rights, duties and obligations hereunder shall not be assigned, transferred, delegated or sublicensed by any party hereto without the prior written consent of the other party; provided, however, that the Investor shall be entitled to transfer Registrable Securities to one or more of their affiliates and, solely in connection therewith, may assign their rights hereunder in respect of such transferred Registrable Securities, in each case, so long as such Investor is not relieved of any liability or obligations hereunder, without the prior consent of the Company. Any transfer or assignment made other than as provided in the first sentence of this Section 3.5 shall be null and void. Subject to the foregoing and except as otherwise provided herein, the provisions of this Agreement shall inure to the benefit of, and be binding upon, the successors, permitted assigns, heirs, executors and administrators of the parties hereto. The Company shall not consummate any recapitalization, merger, consolidation, reorganization or other similar transaction whereby stockholders of the Company receive (either directly, through an exchange, via dividend from the Company or otherwise) equity (the "Other Equity") in any other entity (the "Other Entity") with respect to Registrable Securities hereunder, unless prior to the consummation thereof, the Other Entity assumes, by written instrument, the obligations under this Agreement with respect to such Other Equity as if such Other Equity were Registrable Securities hereunder.

Entire Agreement. This Agreement, together with any exhibits hereto, constitute the entire agreement between the parties relating to the subject matter hereof and all previous agreements or arrangements between the parties, written or oral, relating to the subject matter hereof are superseded.

Waiver. No failure on the part of either party hereto to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of either party hereto in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver thereof; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

Severability. If any part of this Agreement is declared invalid or unenforceable by any court of competent jurisdiction, such declaration shall not affect the remainder of the Agreement and the invalidated provision shall be revised in a manner that shall render such provision valid while preserving the parties' original intent to the maximum extent possible.

Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement. All references in this Agreement to sections, paragraphs and exhibits shall, unless otherwise provided, refer to sections and paragraphs hereof and exhibits attached hereto. References to any section in an Other RRA shall be deemed to refer to the equivalent section in the event of any amendment thereto.

Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be enforceable against the parties that execute such counterparts (including by facsimile or other electronic means), and all of which together shall constitute one instrument.

Term and Termination. The Investor's rights to demand the registration of the Registrable Securities under this Agreement, as well as the Company's obligations hereunder other than pursuant to Section 2.6 hereof, shall terminate automatically once all Registrable Securities cease to be Registrable Securities pursuant to the terms of this Agreement.

*[Remainder of Page Intentionally Left Blank; Signature Page Follows]*

IN WITNESS WHEREOF, the parties hereto have executed this Registration Rights Agreement effective as of the day, month and year first above written.

**PRELUDE THERAPEUTICS INCORPORATED**

By: /s/ Kris Vaddi, Ph.D.  
Name: Kris Vaddi, Ph.D.  
Title: Chief Executive Officer

IN WITNESS WHEREOF, the parties hereto have executed this Registration Rights Agreement effective as of the day, month and year first above written.

INVESTOR:

**INCYTE CORPORATION**

By: /s/ William Meury  
Name: William Meury  
Title: President and CEO

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [\*\*\*] INDICATES THAT INFORMATION HAS BEEN REDACTED.

Exhibit 10.15

## PRELUDE THERAPEUTICS INCORPORATED CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (this “**Agreement**”) is entered into as of November 4, 2025 (the “**Effective Date**”) between **Prelude Therapeutics Incorporated**, a Delaware corporation with its principal place of business at 175 Innovation Boulevard, Wilmington, Delaware 19805 USA (“**Company**”) and **Jane Huang, M.D.**, USA (“**Consultant**”). Company desires to retain Consultant to perform certain consulting activities as described below, and Consultant desires to serve as a consultant to Company and perform such activities under the terms of this Agreement.

NOW, THEREFORE, Consultant and Company agree as follows:

### 1. SERVICES AND COMPENSATION.

(a) Consultant agrees to act as a consultant to Company with respect to such matters and projects as are mutually agreed from time to time by and between Consultant and Company, and perform the services described on Exhibit A (collectively, “**Services**”).

(b) Company agrees to pay Consultant the compensation set forth on Exhibit A for the performance of the Services. All fees and other amounts set forth on Exhibit A, if any, are stated, and are payable, in U.S. dollars. Unless otherwise provided in Exhibit A, Consultant will invoice Company on a monthly basis, within 15 days of the end of the applicable calendar month, for all fees and expenses payable to Consultant with respect to such calendar month in a form prescribed by Company. Company will pay each such invoice within thirty (30) days following receipt thereof, except for any amounts that Company disputes in good faith. The parties will use their respective commercially reasonable efforts to promptly resolve any such payment disputes.

(c) To the extent that Consultant is required to perform Services at or using any Company facility or resources, Consultant will first obtain from Company, and comply with, Company’s workplace, computer and security policies and procedures.

### 2. CONFIDENTIALITY.

(a) “**Confidential Information**” means any proprietary information technical data, trade secrets or know-how, including, but not limited to, research and product plans, products, services, markets, developments, inventions, processes, formulas, technology, marketing, finances or other business information disclosed to Consultant by Company either directly or indirectly in writing, orally or otherwise. Confidential Information also includes all Inventions (as defined below) and any other information or materials generated in connection with the Services.

(b) Consultant shall not, during or subsequent to the term of this Agreement, use any Confidential Information for any purpose whatsoever other than the performance of the Services on behalf of Company, or disclose Confidential Information to any third party. Consultant agrees that Confidential Information shall remain the sole property of Company. Consultant further agrees to maintain the

Confidential Information in strict confidence and to take all reasonable precautions to prevent any unauthorized disclosure or use of Confidential Information. Notwithstanding the above, Consultant's obligation under this Section 2(b) relating to Confidential Information shall not apply to information which

(i) is rightfully known to Consultant at the time of disclosure to Consultant by Company as evidenced by written records of Consultant, (ii) has become publicly known and made generally available through no wrongful act of Consultant, or (iii) has been rightfully received by Consultant from a third party authorized to make such disclosure. Nothing in this Section 2 or otherwise in this Agreement shall limit or restrict in any way Consultant's immunity from liability for disclosing Company's trade secrets as specifically permitted by 18 U.S. Code Section 1833, the pertinent provisions of which are attached hereto as Exhibit B.

(c) Consultant agrees that Consultant will not, during the term of this Agreement, improperly use or disclose to Company any proprietary information or trade secrets of any former or current employer or other person or entity to which Consultant has a duty to keep in confidence such information and that Consultant will not bring onto the premises of Company any unpublished document or proprietary information belonging to such employer, person or entity unless consented to in writing by the same.

(d) Consultant recognizes that Company has received and in the future will receive from third parties their confidential or proprietary information subject to a duty on Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. Consultant agrees that Consultant owes Company and such third parties, during the term of this Agreement and thereafter, a duty to hold all such confidential or proprietary information in the strictest confidence and not to disclose it to any person, firm or corporation or to use it except as necessary in carrying out the Services for Company consistent with Company's agreement with such third party.

(e) Upon written request by the Company at the termination of this Agreement, or upon Company's earlier written request, Consultant will deliver to Company all Confidential Information and Company's property relating thereto and all tangible embodiments thereof, in Consultant's possession or control.

### 3. OWNERSHIP.

(a) Consultant agrees to assign and does hereby irrevocably assign to Company all right, title and interest in and to any information (including, without limitation, business plans and/or business information), technology, know-how, materials, deliverables, works of authorship, documents, notes, records, designs, ideas, inventions, improvements, devices, developments, discoveries, compositions, trade secrets, processes, methods and/or techniques, whether or not patentable or copyrightable, that are conceived, reduced to practice or made by Consultant alone or jointly with others in the performance of the Services or through the use of Confidential Information (collectively, "**Inventions**"), including all worldwide patent rights (including patent applications and disclosures), copyright rights, mask work rights, trade secret rights, know-how, and any and all other intellectual property or proprietary rights (collectively, "**Intellectual Property Rights**") therein.

(b) Consultant agrees to sign, execute and acknowledge or cause to be signed, executed and acknowledged without cost, but at the expense of Company, any and all documents and to perform such acts as may be necessary, useful or convenient for the purposes of perfecting the foregoing assignments and obtaining, enforcing and defending Intellectual Property Rights in any and all countries with respect to Inventions. It is understood and agreed that Company or Company's designee shall have the sole right, but not the obligation, to prepare, file, prosecute and maintain patent applications and patents worldwide with respect to Inventions.

(c) Upon the written request by the Company at the termination of this Agreement, or upon Company's or Consultant earlier written requests, Consultant will deliver to Company all property relating to, and all tangible embodiments of, Inventions in Consultant's possession or control.

(d) Consultant agrees that if, in the course of performing the Services, Consultant incorporates into any Invention developed hereunder any invention, improvement, development concept, discovery or other proprietary subject matter owned by Consultant or in which Consultant has an interest ("**Item**"), Consultant will inform Company in writing thereof, and Company is hereby granted and shall have a non-exclusive, royalty-free, perpetual, irrevocable, worldwide license to make, have made, modify, reproduce, display, use and sell such Item as part of or in connection with the exploitation of such Invention.

(e) Consultant agrees that if Company is unable because of Consultant's unavailability, mental or physical incapacity, or for any other reason, to secure Consultant's signature to apply for or to pursue any application or registration for any Intellectual Property Rights covering any Invention, then Consultant hereby irrevocably designates and appoints Company and its duly authorized officers and agents as Consultant's agent and attorney-in-fact, to act for and in Consultant's behalf to execute and file any such applications and to do all other lawfully permitted acts to further the prosecution and issuance of such Intellectual Property Rights thereon with the same legal force and effect as if executed by Consultant.

**4. REPORTS.** Consultant agrees, from time to time during the term of this Agreement, to keep Company advised as to Consultant's progress in performing the Services and, as reasonably requested in writing by Company, prepare written reports with respect thereto. It is understood that the time required in the preparation of such written reports shall be considered time devoted to the performance of the Services by Consultant. All such reports prepared by Consultant shall be the sole property of Company.

## **5. TERM AND TERMINATION.**

(a) This Agreement will commence on November 4, 2025, and will terminate on Sept 15, 2026, during which time the Parties agree that there is a continuation of "Service" as defined in section 25.6 of the Company's 2020 Equity Incentive Plan. All terms and conditions of the Company's 2020 Equity Incentive Plan remain in full force and effect.

(b) The Company may terminate this Agreement at any time to the extent the Company, in its sole discretion, believes there is a breach of section 9 of this Agreement.

(c) Upon termination of this Agreement, all rights and duties of the parties hereunder shall cease except: (i) Consultant will promptly deliver to Company all Inventions, including all work in progress on any Inventions not previously delivered to Company, if any; (ii) Company shall be obliged to pay, within thirty (30) days after receipt of Consultant's final statement, all amounts owing to Consultant for unpaid Services completed by Consultant and related expenses, if any, in accordance with Section 1; and (iii) Sections 2, 3, 5(c), 6, 7, 8 and 10 shall survive termination of this Agreement.

## **6. RELATIONSHIP OF THE PARTIES.**

(a) Independent Contractor. Consultant is an independent contractor and nothing in this Agreement will be construed as establishing an employment or agency relationship between Company and Consultant. Consultant has no authority to bind Company by contract or otherwise. Consultant will perform Services under the general direction of Company, but Consultant will determine, in Consultant's sole discretion, the manner and means by which Services are accomplished, subject to the requirement that Consultant will at all times comply with applicable law.

(b) Taxes and Employee Benefits. **Consultant acknowledges and agrees that Consultant is**

**obligated to report as income, and pay all applicable taxes with respect to, all compensation received by Consultant pursuant to this Agreement.** Consultant will not be entitled to any benefits paid or made available by Company to its employees, including, without limitation, any vacation or illness payments, or to participate in any plans, arrangements or distributions made by Company pertaining to any bonus, stock option, profit sharing, insurance or similar benefits. Consultant will indemnify and hold Company harmless from and against all damages, liabilities, losses, penalties, fines, expenses and costs (including reasonable fees and expenses of attorneys and other professionals) arising out of or relating to any obligation imposed by law on Company to pay any withholding taxes, social security, unemployment or disability insurance or similar items in connection with compensation received by Consultant pursuant to this Agreement. Consultant acknowledges that Company will not carry any liability insurance on behalf of Consultant.

(c) Transparency Reporting. Consultant agrees that Company or its designee may report to federal and/or state authorities such compensation, payments, and other transfers of value made to Consultant hereunder that Company, in its sole discretion, deems necessary in order to comply with transparency reporting requirements pursuant to 42 U.S.C. § 1320a-7h (commonly known as the “Physician Payment Sunshine Act”) and similar state laws, and their respective implementing regulations.

## **7. WARRANTIES**

(a) No Debarment. Consultant represents and warrants that Consultant has not been debarred under Section (a) or (b) of 21 U.S.C. Section 335a and does not appear on the United States Food and Drug debarment list. Consultant represents and warrants that Consultant has not committed any crime or conduct that could result in such debarment or Consultant’s exclusion from any governmental healthcare program. Consultant represents and warrants that, to Consultant’s knowledge, no investigations, claims or proceedings with respect to any such crimes or conduct are pending or threatened against Consultant. Consultant agrees and undertakes to promptly notify Company if Consultant becomes debarred or proceedings have been initiated against Consultant with respect to debarment, whether such debarment or initiation of proceedings occurs during or after the term of this Agreement.

(b) Performance Standard. Consultant represents and warrants that Consultant has the requisite training, background, experience, technical knowledge and skills to perform the Services and that Consultant will perform the Services in a thorough and professional manner, consistent with professional and industry standards and in compliance with all applicable laws and regulations.

**8. Employer Acknowledgment. Consultant represents and warrants that Consultant has disclosed this consulting arrangement to Consultant’s current (or, if applicable, future) employer and has confirmed that such employer does not object to Consultant’s performance of the Services hereunder.**

**9. ARBITRATION AND EQUITABLE RELIEF**. Any dispute, claim or controversy arising out of or relating to this Agreement, or the breach, termination, enforcement, interpretation or validity thereof, including the determination of the scope or applicability of this agreement to arbitrate, shall be finally determined by binding arbitration in Delaware before one arbitrator. The arbitration shall be administered by JAMS pursuant to its Streamlined Arbitration Rules and Procedures. The costs of the arbitration, including administrative and arbitrators’ fees, shall be shared equally by the parties, and each party shall bear its own costs and attorneys’ and witness’ fees incurred in connection with the arbitration. Judgment on the Award may be entered in any court having jurisdiction. The parties agree that, any provision of applicable law notwithstanding, they will not request and the arbitrator shall have no authority to award, punitive or exemplary damages against either party. This Section 8 shall not preclude parties from seeking provisional remedies in aid of arbitration from a court of appropriate jurisdiction.

**10. INDEMNIFICATION.** In the performance of services under this Agreement, the Consultant shall be obligated to act in good faith but shall not be liable to the Company for errors in judgment that are not the result of gross negligence or willful misconduct. The Company agrees to indemnify and hold the Consultant harmless from and against any and all losses, claims, expenses, damages, or liabilities, joint or several, to which the Consultant may become subject (including the costs of any investigation and all reasonable attorneys' fees and costs) or incurred by the Consultant, to the fullest extent lawful, in connection with any pending or threatened litigation, legal claim, or proceeding arising out of or in connection with the services rendered by the Consultant under this Agreement; provided, however, that the foregoing indemnity shall not apply to any such losses, claims, related expenses, damages or liabilities arising out of or in connection with the Consultant's gross negligence, willful misconduct or fraud.

**11. LIMITATION OF LIABILITY; ACTIONS.** IN NO EVENT SHALL THE CONSULTANT BE LIABLE UNDER THIS AGREEMENT TO THE OTHER PARTY FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, STATUTORY, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, LOSS OF USE, LOSS OF TIME, INCONVENIENCE, LOST BUSINESS OPPORTUNITIES, DAMAGE TO GOOD WILL OR REPUTATION, AND COSTS OF COVER, REGARDLESS OF WHETHER SUCH LIABILITY IS BASED ON BREACH OF CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, AND EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR SUCH DAMAGES COULD HAVE BEEN REASONABLY FORESEEN. THIS SECTION SHALL SURVIVE THE TERMINATION OF THE AGREEMENT

**12. CONFLICTING OBLIGATIONS.** Consultant hereby represents, warrants and certifies that Consultant has no outstanding agreement, commitment or obligation that is in conflict with any of the provisions of this Agreement, or that would preclude Consultant from complying with the provisions hereof or otherwise create an actual or potential conflict of interest with Consultant's obligations under this Agreement, and further certifies that Consultant will not enter into any such conflicting agreement during the term of this Agreement. Consultant agrees to promptly notify Company if any potential conflict arises during the term of this Agreement. Subject to written waivers that may be provided by Company upon request, which shall not be unreasonably withheld, Consultant agrees that, during the term of this Agreement, Consultant will not directly provide any services in the Field of Interest (as defined on Exhibit A) to any other business or commercial entity, Consultant shall list on Exhibit C any other companies for whom Consultant is providing services ("Company Approved Outside Companies"), The Services performed hereunder will not be conducted on time that is required to be devoted to any other third party. Consultant shall not use the funding, resources and facilities of any other third party, without the prior written consent of Company, to perform Services hereunder and shall not perform the Services hereunder in any manner that would give any third party rights or access to the product of such Services. Without limiting the foregoing, Consultant agrees to use his or her best efforts (A) to segregate Consultant's Services performed under this Agreement from Consultant's work done for the Outside Companies and any other third party so as to minimize any questions of disclosure of, or rights under, any inventions, (B) to notify Company if at any time Consultant believes that such questions may result from his or her performance under this Agreement and (C) to assist Company in fairly resolving any questions in this regard which may arise.

**13. NOTICES.**

Any required notice shall be given in writing by customary means with receipt confirmed at the address of each party set forth below, or to such other address as either party may substitute by written notice to the other. Notices delivered by USPS or courier services shall be

deemed as received as of the date of delivery as evidenced by return receipt or other proof of delivery. Notices sent via email are not permitted.

Company: Prelude Therapeutics Incorporated  
175 Innovation Boulevard Wilmington, Delaware 19805  
USA  
Attn: Contracts Department [contracts@preludetx.com](mailto:contracts@preludetx.com)

Consultant: Jane Huang, M.D.  
[\*\*\*]

**14. GENERAL.** This Agreement, including the Exhibits hereto, is the sole agreement and understanding between Company and Consultant concerning the subject matter hereof, and it supersedes all prior agreements and understandings with respect to such matter. Any required notice shall be given in writing by customary means with receipt confirmed at the address of each party set forth below, or to such other address as either party may substitute by written notice to the other. Consultant shall not subcontract any portion of Consultant's duties under this Agreement without the prior written consent of Company. Neither this Agreement nor any right hereunder or interest herein may be assigned or transferred by Consultant without the prior written consent of Company. Company may assign this Agreement to any entity that succeeds to substantially all of the business or assets of Company. This Agreement shall be governed by the laws of the State of Delaware, without reference to its conflicts of law principles. This Agreement may only be amended or modified by a writing signed by both parties. Waiver of any term or provision of this Agreement or forbearance to enforce any term or provision by either party shall not constitute a waiver as to any subsequent breach or failure of the same term or provision or a waiver of any other term or provision of this Agreement. In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision, provided that no such severability shall be effective if it materially changes the economic benefit of this Agreement to either Company or Consultant. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together shall constitute one and the same instrument. Once signed, any reproduction of this Agreement made by reliable means (e.g., photocopy, facsimile) is considered an original.

*[- signature page follows -]*

IN WITNESS WHEREOF, the parties hereto have executed this Agreement, effective November 4, 2025.

**PRELUDE THERAPEUTICS INCORPORATED JANE HUANG, M.D.**

By: /s/ Michele Porreca  
Name: Michele Porreca  
Title: Chief People Officer  
Date: 03 November 2025

By: /s/ Jane Huang  
Name: Jane Huang  
Title: President and CMO  
Date: 03 November 2025

## EXHIBIT A

### SERVICES AND COMPENSATION

1. Services. Consultant will render to Company the following Services:

- [\*\*\*]

2. Accommodations.

- **Company Equipment.** Consultant acknowledges that they have retained possession of certain equipment previously provided to them as a full-time employee of the Company. The Company hereby permits Consultant to retain and use such equipment in perpetuity. At the termination of the agreement, Consultant will remove all company related materials from the equipment.
- **Office Space.** Provided the space remains available for Prelude's use, Consultant may continue to utilize the [\*\*\*] office space for the ease of providing consulting services located at [\*\*\*], through the expiration of the existing lease, which is scheduled to terminate on [\*\*\*]. Consultant acknowledges that such use is subject to the terms and conditions of the lease agreement governing the premises, and Consultant shall comply with all applicable rules, policies, and obligations thereunder. Company shall have no obligation to extend or renew such lease, nor to provide alternate office space past [\*\*\*].

2. Compensation.

- **Equity Awards.** Consultant acknowledges and agrees that Consultant has been granted certain equity awards by Company pursuant to the Company's equity incentive plan(s) and the applicable award agreements (collectively, the "Equity Awards"). For purposes of such Equity Awards, and notwithstanding any contrary provision in the applicable plan or award agreements, Consultant's continuous service with the Company shall be deemed to continue during the term of this Agreement, and the Equity Awards shall continue to vest in accordance with their existing terms and conditions for so long as this Agreement remains in effect and Consultant continues to provide Services to the Company. For the avoidance of doubt, except as expressly provided herein, nothing in this Agreement alters the terms of the applicable equity incentive plan(s) or award agreements, including without limitation provisions regarding exercise, settlement, termination, or expiration of the Equity Awards.
- Company will pay Consultant \$750 per hour. Total of all invoices shall not exceed \$150,000 without prior written approval by the Company's Chief Executive Officer

- Consultant shall maintain documentation of the hours spent in performing the Services, and a description of the activities performed during each interval. Such documentation shall be required to be submitted to Company for payment.
- Company will reimburse Consultant for all preapproved and properly vouched travel and out-of-pocket expenses incurred by Consultant in performing Services pursuant to this Agreement that are pre-approved by Company.
- Consultant will submit to Company all statements for expenses incurred and Services performed on a monthly basis in a form prescribed by Company.
- The compensation provided for hereunder has been determined by the parties through good faith and arms-length bargaining to be the fair market value of the Services described in this Exhibit A. No amount paid or to be paid hereunder is intended to be, nor shall it be construed as, an offer or payment made, whether directly or indirectly, overtly or covertly, to induce the referral of patients, the purchase, prescribing, or order of any item or service, or the recommending or arranging for the purchase, prescribing, or order of any item or service.

**EXHIBIT B**

**DEFEND TRADE SECRETS ACT, 18 U.S. CODE § 1833 NOTICE:**

This exhibit has been omitted pursuant to Item 601(a)(5).

**EXHIBIT C**

**COMPANY APPROVED OUTSIDE COMPANIES**

This exhibit has been omitted pursuant to Item 601(a)(5).

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-249032) pertaining to the 2016 Stock Incentive Plan, 2020 Equity Incentive Plan, and 2020 Employee Stock Purchase Plan of Prelude Therapeutics Incorporated,
- (2) Registration Statement (Form S-8 Nos. 333-254349, 333-263642, 333-270549, 333-277122, and 333-285662) pertaining to the 2020 Equity Incentive Plan and 2020 Employee Stock Purchase Plan of Prelude Therapeutics Incorporated,
- (3) Registration Statement (Form S-3 No. 333-261019) of Prelude Therapeutics Incorporated,
- (4) Registration Statement (Form S-3 No. 333-277123) of Prelude Therapeutics Incorporated,
- (5) Registration Statement (Form S-3 No. 333-279829) of Prelude Therapeutics Incorporated, and
- (6) Registration Statement (Form S-3 No. 333-292048) of Prelude Therapeutics Incorporated;

of our report dated March 10, 2026, with respect to the financial statements of Prelude Therapeutics Incorporated included in this Annual Report (Form 10-K) of Prelude Therapeutics Incorporated for the year ended December 31, 2025.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania  
March 10, 2026

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**CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER  
THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Krishna Vaddi, certify that:

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

Date: March 10, 2026

/s/ Krishna Vaddi  
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Krishna Vaddi, Ph.D.  
Chief Executive Officer and Director  
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER  
THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Bryant Lim, certify that:

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

Date: March 10, 2026

/s/ Bryant Lim

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Bryant Lim  
Chief Financial Officer  
(Principal Accounting and Financial Officer)

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

I, Krishna Vaddi, Chief Executive Officer of Prelude Therapeutics Incorporated (the “Company”), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2025 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 10, 2026

/s/ Krishna Vaddi

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Krishna Vaddi, Ph.D.  
Chief Executive Officer and Director  
(Principal Executive Officer)

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

I, Bryant Lim, Chief Financial Officer of Prelude Therapeutics Incorporated (the “Company”), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2025 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 10, 2026

/s/ Bryant Lim

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Bryant Lim

Chief Financial Officer

(Principal Accounting and Financial Officer)

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