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: 001-39980

Sensei Biotherapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**83-1863385**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1405 Research Boulevard, Suite 125 Rockville, MD	**20850**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (240) 243-8000

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, $0.0001 par value per share	SNSE	The Nasdaq Stock Market LLC

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

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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

Indicate by check mark whether any of those error 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 ☒

As of June 30, 2025 (the last business day of the Registrant's second fiscal quarter), the Registrant's aggregate market value of its voting common equity held by non-affiliates was approximately $7.1 million based on the closing sale price of $8.58 per share as reported on the Nasdaq Capital Market on that date. The number of shares of Registrant's Common Stock outstanding as of March 23, 2026 was 1,340,281.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement, to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934, for its 2026 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

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Cautionary Notice Regarding Forward-Looking Statements

All statements other than statements of historical fact included in this Annual Report on Form 10-K, or the Report, including, without limitation, statements under "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" regarding our financial position, business strategy and the plans and objectives of management for future operations, are forward-looking statements. When used in this Report, words and phrases such as "aim," "anticipate," "assume," "believe," "can," "continue," "could," "designed to," "estimate," "evaluate," "expect," "explore," "intend," "intended to," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "pursue," "seek," "should," "to be," "will," and "would," or the negative of such terms or other similar expressions, as they relate to us or our management, identify forward-looking statements.

Any statements in this Report, or incorporated herein, about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. These forward-looking statements include statements regarding:

- the ability of our preclinical studies and clinical trials to demonstrate acceptable safety and efficacy of our product candidates;
- our beliefs regarding the scientific rationale for multi-node inhibition of the PI3K/AKT/mTOR pathway, including the potential for deeper and more durable pathway suppression compared to single-node inhibition, and the clinical utility of our approach across patient populations regardless of mutational status;
- our beliefs regarding PIKTOR's efficacy and tolerability profile relative to other PI3K/AKT/mTOR pathway agents, which are based on cross-trial comparisons involving differences in trial design, patient populations, endpoints, and grading criteria;
- business disruptions affecting the initiation, patient enrollment, development and operation of our clinical trials;
- the timing, progress and results of preclinical studies and clinical trials for our current and future product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- the timing, scope and likelihood of regulatory filings and approvals, including Investigational New Drug, or IND, submissions for our product candidates;
- our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical trials;
- our ability to successfully integrate the operations of the Company and Faeth Therapeutics and to realize the anticipated benefits of the merger, including the advancement of the combined pipeline and retention of key personnel;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our expectations regarding the approval and use of our product candidates as first, second or subsequent lines of therapy or in combination with other drugs;
- our expectations regarding the competitive landscape for PI3K/AKT/mTOR pathway therapies, including the anticipated clinical development, regulatory outcomes, and commercial positioning of competing product candidates, and our ability to compete effectively against such products, including other multi-node inhibitors and mutant-selective inhibitors;
- the characteristics and therapeutic effects of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to recognize the benefits of our acquisition of Faeth Therapeutics;
- our plans relating to the further development of our product candidates, including additional indications we may pursue;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering product candidates we may develop, including the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;

- our reliance on third parties to manufacture and conduct clinical trials of our product candidates;
- our ability to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the pricing and reimbursement of our product candidates we may develop, if approved;
- the rate and degree of market acceptance and clinical utility of our current and future product candidates;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance and our ability to effectively manage our anticipated growth;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the impact of laws and regulations;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing resources and the proceeds of any offerings of our securities.

These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to revise any forward-looking statements to reflect events or developments occurring after the date of this Report, even if new information becomes available in the future. You should refer to the Risk Factors section of this Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements.

PART I

Item 1. Business.

In this Annual Report, unless the context otherwise dictates, the terms (i) "we," "us," "our," "Sensei," the "Company" and other similar terms refer to the business and operations of Sensei Biotherapeutics, Inc. and its consolidated subsidiaries for periods prior to the Acquisition (as defined below) and to Sensei Biotherapeutics, Inc. and its consolidated subsidiaries, including Faeth Therapeutics for periods after the Acquisition; (ii) "Faeth HoldCo" refers to Faeth Holdings Therapeutics, Inc., (iii) "Faeth Subsidiary" refers to Faeth Therapeutics, LLC, a wholly owned subsidiary of Faeth HoldCo, (iv) "Faeth" or "Faeth Therapeutics" refer collectively to Faeth HoldCo and Faeth Subsidiary and (v) "Acquisition" refers to the acquisition by the Company of Faeth Therapeutics pursuant to that Agreement and Plan of Merger, dated February 17, 2026, by and among the Company, Sapphire First Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, Sapphire Second Merger Sub, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company, Faeth HoldCo and Faeth Subsidiary.

Overview

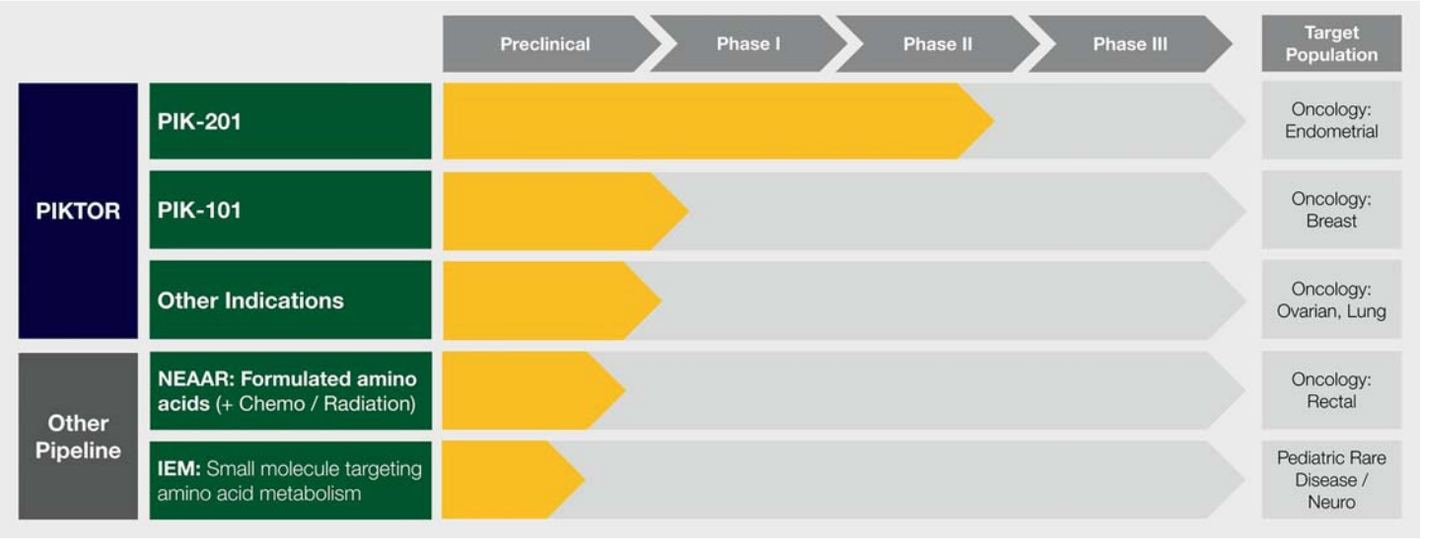
We are a clinical-stage biotechnology company focused on improving outcomes for cancer patients through multi-node inhibition of critical oncogenic pathways. On February 17, 2026, we completed the acquisition of Faeth Therapeutics, a clinical-stage biotechnology company developing multi-node therapies that target tumor metabolism and signaling. The Acquisition brought Faeth's lead asset, PIKTOR, a proprietary investigational all-oral combination of serabelisib and sapanisertib that inhibits multiple nodes of the PI3K/AKT/mTOR pathway, into our pipeline. In connection with the Acquisition, we received $200 million in gross proceeds from a private placement financing, or the 2026 Private Placement, from a broad syndicate of investors, including several leading life sciences funds, including B Group Capital, Balyasny Asset Management, Columbia Threadneedle Investments, Cormorant Asset Management, Fairmount, Logos Capital, RA Capital Management, and Vivo Capital, to advance PIKTOR through key clinical milestones. For additional information regarding the terms of the Acquisition and the 2026 Private Placement, see Note 15 to the consolidated financial statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in this Annual Report.

Following the Acquisition, our lead program is PIKTOR, an investigational multi-node inhibitor, or MNI, of the PI3K/AKT/mTOR pathway in development for endometrial and breast cancer. The PI3K/AKT/mTOR pathway is dysregulated in up to 50% of all solid tumors, making it one of the most prevalent therapeutic targets in oncology. Despite this, currently approved therapies — all of which target only a single pathway node — have produced limited clinical benefits, often accompanied by toxicities that have constrained their utilization. Our core scientific thesis is that simultaneously suppressing multiple nodes of a pathway produces deeper, more durable tumor suppression than targeting any single-node alone, which we believe may also enable lower drug dosing, potentially contributing to an improved tolerability profile.

PIKTOR is currently being evaluated in an ongoing Phase 2 trial in second-line advanced endometrial cancer (Study FTH-PIK-201), with topline data anticipated by year-end 2026, and we intend to initiate a Phase 1b trial in HR+/HER2- advanced breast cancer (Study FTH-PIK-101) by the first half of 2026.

Faeth was co-founded in 2019 by Anand Parikh and Oliver Maddocks, PhD, together with scientific founders Lewis Cantley, PhD, the discoverer of the PI3K pathway, Siddhartha Mukherjee, MD, DPhil, Karen Vousden, PhD, Scott Lowe, PhD, and Greg Hannon, PhD. We are led by an experienced management team with expertise spanning cancer biology, translational research, clinical drug development, regulatory affairs and corporate strategy gained through prior roles within both biotechnology and large pharmaceutical companies as well as academia.

Our Pipeline



Corporate Strategy

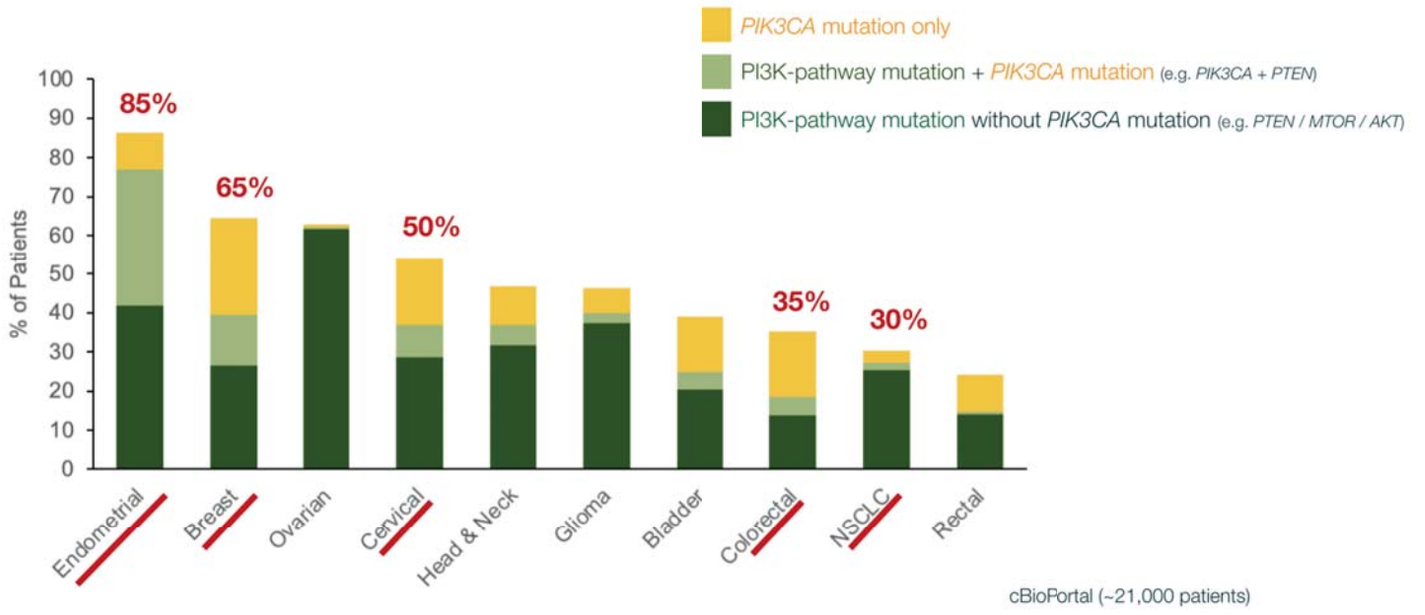
Our mission is to improve the lives of patients by developing novel therapeutics to treat some of the most devastating types of cancer. Our strategy to achieve these goals centers on the following development priorities:

- We intend to establish PIKTOR's initial therapeutic proof of concept in endometrial cancer through our ongoing Phase 2 trial (FTH-PIK-201), with topline data anticipated by year-end 2026 and longer-term follow-up data in 2027.
- Concurrently, we plan to broaden PIKTOR's development into advanced HR+/HER2- breast cancer through Study FTH-PIK-101, with trial initiation targeted for the first half of 2026, interim dose escalation data and expansion cohort initiation in 2027, and expansion cohort data in 2028.
- Beyond these near-term priorities, we intend to explore PIKTOR's potential as a first-line treatment across our targeted indications. We believe that PIKTOR's convenient oral formulation, potentially differentiated therapeutic profile and demonstrated synergy in combination with many relevant agents in our targeted tumor types may benefit patients at the earliest stages of disease.
- We may also pursue development in additional indications, including ovarian cancer and genetically defined subtypes of lung cancer, as well as advance additional pipeline candidates beyond PIKTOR, including our NEAAR and IEM programs. In the future we intend to utilize our deep expertise in cancer and metabolic disease to identify additional compelling development opportunities.

The PI3K/AKT/mTOR Pathway and the Case for Multi-Node Inhibition

Pathway Biology

The PI3K/AKT/mTOR pathway is a vital, complex intracellular signaling network that plays a central role in regulating cellular metabolism, proliferation and survival by activating either pro-growth or regulatory signals in response to nutrient availability and extracellular stimuli. Given its importance to these key functions of healthy cells, it is not surprising that dysregulated pathway activity can play an integral role in tumorigenesis, proliferation and treatment resistance as many validated cancer targets, in their natural state, govern these processes. It is estimated that the growth of up to 50% of all solid tumors is driven or amplified by the aberrant activation of the PI3K/AKT/mTOR pathway, as depicted below.



Source: cBioPortal for Cancer Genomics (approximately 21,000 patients). Cerami et al., Cancer Discov. 2012; Gao et al., Sci. Signal, 2013. NSCLC: non-small cell lung cancer.

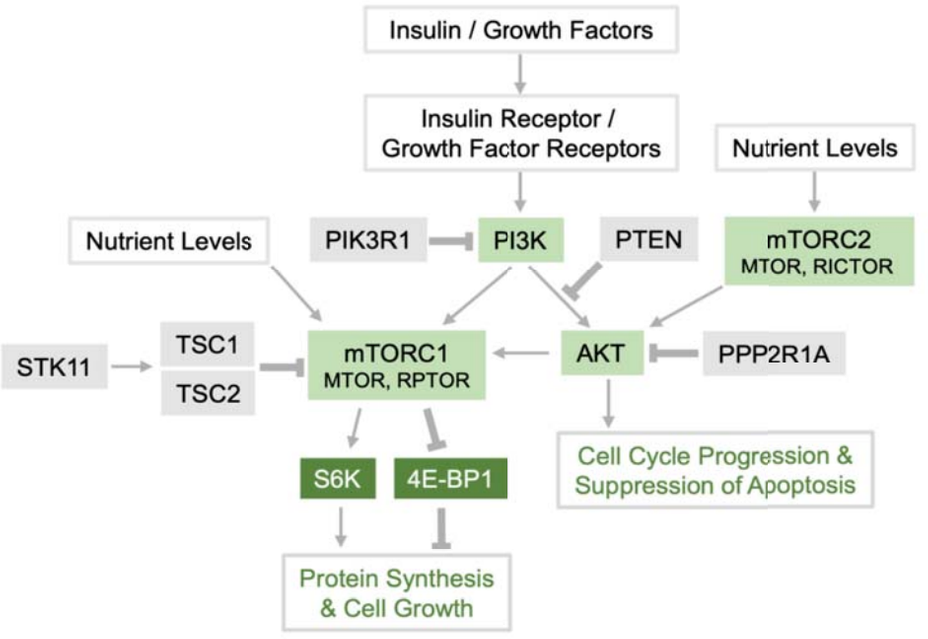
The key components of the pathway are:

Phosphoinositide 3-kinase (PI3K), an upstream node in the pathway which is activated by various growth factor receptors in response to extracellular stimuli to produce either growth or regulatory signals. PI3K is further broken down into four subtypes, or isoforms, that are expressed in different cell types. The PI3K alpha isoform (PI3Kα, encoded by the *PIK3CA* gene) is responsible for either initiating or regulating cellular proliferation.

AKT serine/threonine kinase (AKT), a central coordinator that receives the signals from PI3K and ensures that the cell responds in the appropriate manner based on the nature of the signal.

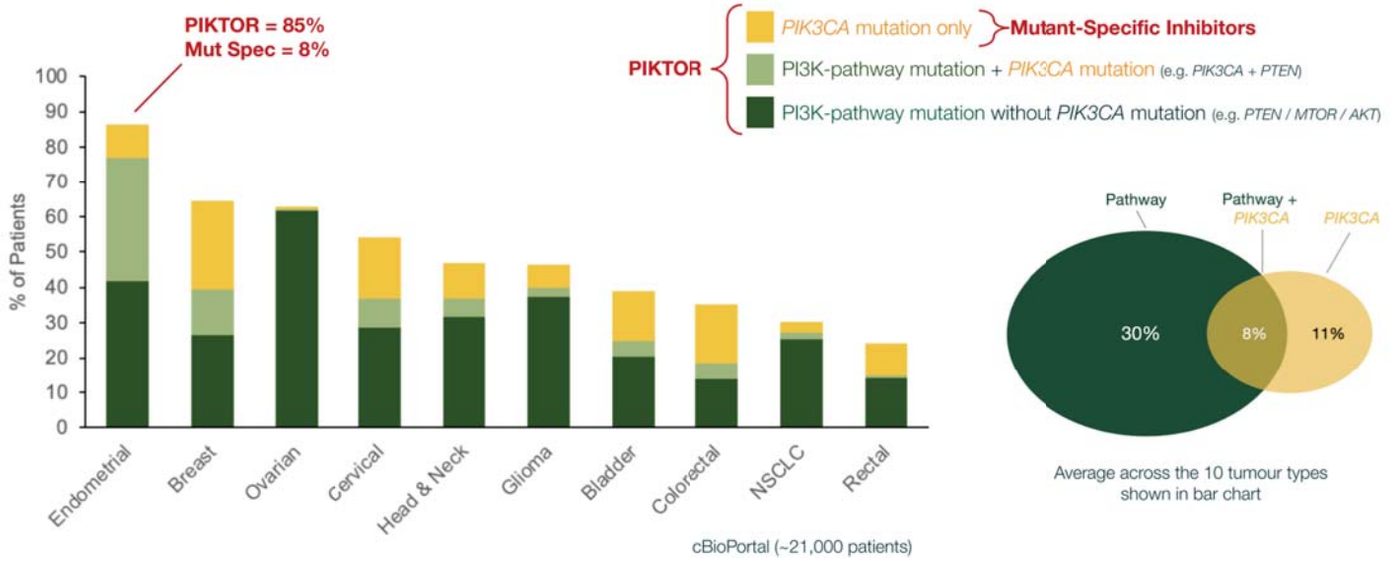
Mechanistic target of rapamycin (mTOR), which orchestrates cell growth, proliferation and survival by determining whether cells grow and divide or conserve their resources in response to signals from PI3K/AKT. mTOR operates through two distinct complexes: mTORC1 and mTORC2. mTORC1 is activated when nutrients are abundant, driving cell growth and proliferation. mTORC2 plays a role in controlling the full activation of AKT in either a proliferative or regulatory state.

Phosphatase and tensin homolog (PTEN), a pathway regulator that counteracts PI3K's pro-growth actions to ensure the PI3K/AKT pathway's pro-growth activities are appropriately controlled in healthy tissues.



The PI3K/AKT/mTOR Pathway

Mutation of the *PIK3CA* gene is the most common oncogenic alteration of the PI3K/AKT/mTOR pathway, encompassing approximately 40% of total pathway mutations. However, mutations in any pathway component, which collectively outnumber those to PI3Kα, can also lead to oncogenic activity and the pathway can also be aberrantly activated in support of tumor growth in its non-mutated, "wild type" state either by dysregulated upstream signaling or as an adaptive response to therapy. The pathway's ability to support tumors without its own mutation suggests its clinical relevance may extend beyond those patients with direct pathway mutations.



Broader pathway mutations outnumber PI3Kα

Source: cBioPortal for Cancer Genomics (approximately 21,000 patients). Cerami et al., Cancer Discov. 2012; Gao et al., Sci. Signal, 2013. The "PIKTOR = 85%" figure represents the estimated percentage of PI3K/AKT/mTOR pathway-mutated tumors, across the tumor types depicted, that harbor mutations within the broad pathway nodes addressable by PIKTOR's multi-node mechanism (PI3Kα, mTORC1, mTORC2 and associated pathway components). The "Mut Spec = 8%" figure represents the estimated average percentage of endometrial tumors harboring a PIK3CA mutation as the sole pathway alteration, reflecting the narrower population that may be addressable by mutant-specific PI3Ka inhibitors. The

percentages in the Venn diagram relate to all ten tumor types reflected in the bar chart. These estimates are based on the Company's analysis of publicly available genomic data. NSCLC: non-small cell lung cancer.

Approved Single-Node Inhibitors (SNI) Therapies and Their Limitations

Given the relevance of the PI3K/AKT/mTOR pathway in the context of cancer, considerable effort and resources have been expended to develop pathway inhibitors. These efforts have resulted in the approval of five agents for the treatment of PI3K/AKT/mTOR pathway-associated solid tumors, each of which is a single-node inhibitor, or SNI, of the pathway:

- Alpelisib: selective PI3Kα inhibitor
- Inavolisib: selective PI3Kα inhibitor
- Capivasertib: pan-AKT inhibitor
- Everolimus: mTORC1 inhibitor
- Temsirolimus: mTORC1 inhibitor

The currently approved therapies have focused on single-node inhibition and PI3Kα isoform selectivity in an attempt to improve the class's therapeutic window. Earlier pan-PI3K isoform inhibitors produced numerous trial failures, and one withdrawn approval, due to weak efficacy or immunologic and metabolic toxicities.

The primary factor limiting the effectiveness of these approved treatments is that inhibition of a single pathway node can produce only partial pathway suppression, leaving the remaining nodes available to sustain or reroute oncogenic signaling. This approach, common in cancer drug development and successful in other settings where tumor growth is driven by a single mutated "on/off switch," is inadequate in this setting due to the redundant, distributed signaling capabilities of the PI3K/AKT/mTOR pathway. SNIs, therefore, have only limited impact on many key oncogenic dysregulations and are circumvented by the acute adaptive rerouting of signaling, and due to emergence of additional pathway mutations, both of which arise in response to treatment. SNIs have also been associated with elevated on-target toxicities that have led to either clinical trial discontinuations or restricted commercial uptake.

The MNI Thesis

The discovery and development of targeted therapies for cancer in the early 2000s marked a major innovative breakthrough in cancer treatment and has improved the lives of millions of patients over the past two decades. More than twenty years of experience with these treatments, however, has taught us that cancer's biology is often far too complex to be vanquished by the blockade of single oncogenic mutations.

Our core scientific thesis is that simultaneously suppressing multiple nodes of complex signaling pathways can produce deeper, more durable tumor suppression than targeting any single node alone because it not only can block initial oncogenic mutations but also restrict the development of adaptive resistance mechanisms that emerge in response to treatment. Emerging clinical evidence suggests that SNI-driven suppression may itself promote acquired resistance, further underscoring the need for a more comprehensive approach.

In contrast to single-node inhibition, MNIs are designed to better match the biologic architecture of the PI3K/AKT/mTOR pathway to maintain durable suppression, as they not only inhibit initial dysregulated oncogenic signaling at multiple points but also shut down the "escape routes" that tumors often employ to resist treatment. Because MNI suppresses the pathway more comprehensively, emerging evidence suggests its clinical benefit may extend beyond patients with direct pathway mutations to include tumors where the pathway is aberrantly activated as a resistance mechanism rather than a primary oncogenic driver. This differentiated capability has been reflected in clinical trial data generated by some development stage MNIs relative to the approved SNIs, as discussed further below.

PIKTOR — Our Lead Clinical Candidate

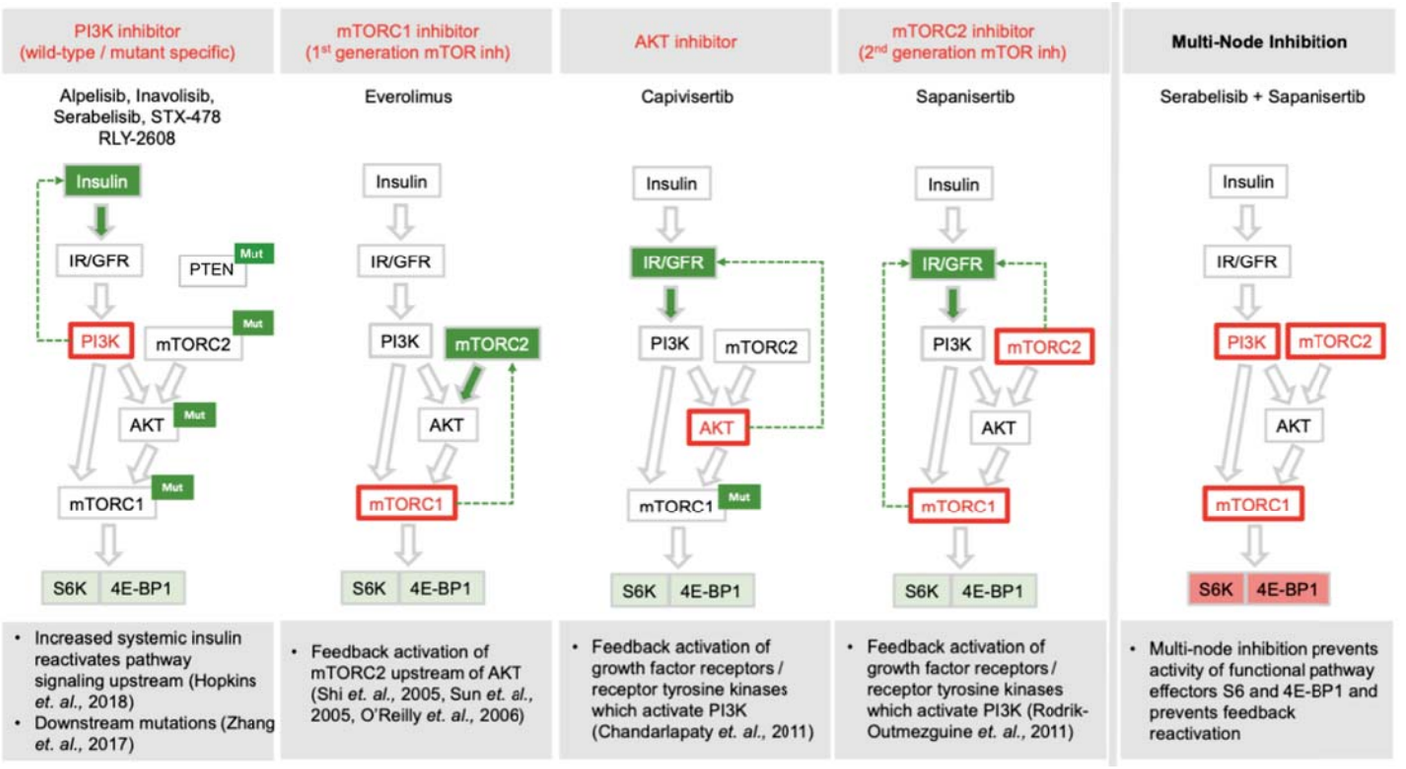
Composition and Mechanism of Action

PIKTOR, our lead clinical candidate, is an oral MNI of the PI3K/AKT/mTOR pathway. PIKTOR is comprised of two independently dosed inhibitors of discrete pathway nodes:

- **Serabelisib**, a selective phosphoinositide 3-kinase alpha (PI3Kα) inhibitor

- **Sapanisertib**, a mammalian target of rapamycin complexes (mTORC) 1 and 2 inhibitor

PIKTOR's design reflects a strategy of vertical pathway blockade, targeting PI3Kα upstream and mTORC1 and mTORC2 downstream, simultaneously addressing oncogenic pathway activation and the adaptive escape routes tumors employ to resist treatment, while suppressing downstream signaling regardless of mutational status. In addition, the selectivity of serabelisib for PI3Kα versus other PI3K isoforms may reduce the risk of off-target toxicities associated with pan-PI3K inhibition.



PIKTOR's Multi-node Mechanism of Action

Source: Tyrakis et al., British Journal of Cancer, 2025; 133: 144–154. Hopkins BD, Pauli C, Du X, Wang DG, Li X, Wu D, et al. Suppression of insulin feedback enhances the efficacy of PI3K inhibitors. Nature. 2018;560:499–503.

Differentiated Product Profile

We believe PIKTOR may have a substantially differentiated clinical profile versus both currently available and developmental treatments for multiple solid tumors, including:

- **Oral MNI mechanism of action**, providing convenient administration relative to IV-based alternatives
- **Favorable emerging tolerability profile**, with rates of hyperglycemia and stomatitis observed in clinical trials to date that compare favorably to those reported for both approved SNIs and other MNIs in development, as described in the "Emerging Safety Profile" section below
- **Potentially best-in-class-potency,** with preclinical data suggesting PIKTOR may achieve pathway suppression at lower concentrations than either approved or developmental competitors
- **Broad anti-tumor impact**, with responses observed across multiple tumor types and mutational profiles, including in patients with no detectable PI3K/AKT/mTOR pathway mutations, suggesting that multi-node inhibition may confer clinical benefit independent of mutational status
- **Selective PI3Kα inhibition** that may avoid immunologic toxicity that has been historically associated with pan-PI3K inhibitors
- **Synergistic activity** with CDK4/6 inhibitors, taxane-based chemotherapy, and potentially selective estrogen receptor degraders, or SERDs, as observed in preclinical models — all of which are important components of current treatment regimens across our targeted tumor types

- **Tunability** that may potentially enable indication-specific dose optimization of each component through independent dosing of serabelisib and sapanisertib

Breast Cancer Cell Line Dose-Response Curve IC_{50} (uM)

Cell Line	PI3K-Pathway Status	HR/HER2 Status	Serabelisib [1]	Sapanisertib [1]	PIKTOR [1]	Gedatolisib [2]	Alpelisib [1]	Everolimus [1]	Capivasertib [1]	RLY-2608 [1]	STX-478 [1]	Inavolisib [1]	Paclitaxel [1]
MDA-MB-361	PIK3CA-E545K, MTOR-E1427Q	HR+/HER2+	3.82	0.010	**0.0075**	**0.023**	1.34	>100	0.879	5.94	2.93	0.162	0.237
T47D	PIK3CA-H1047R	HR+/HER2-	1.34	0.012	**0.0033**	**0.047**	0.20	28.8	0.255	0.61	0.13	0.056	0.009
MCF-7	PIK3CA-E545K	HR+/HER2-	1.33	0.005	**0.0021**	**0.014**	0.407	>100	0.455	1.57	0.63	0.063	0.026
MDA-MB-231	Wild-type PI3K pathway	TNBC (HR-/HER2-)	6.01	0.024	**0.0111**	**0.024**	19.89	14.8	87.5	31.6	>100	>100	0.011
Breast Cancer Average IC50:			3.13	0.013	**0.006**	**0.027**	5.46	60.9	22.3	9.93	25.92	25.1	0.071

Endometrial Cancer Cell Line Dose-Response Curve IC_{50} (uM)

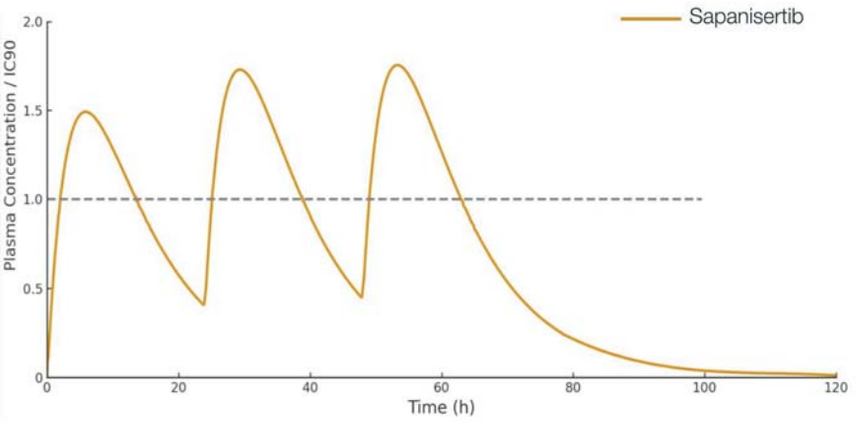
Cell Line	PI3K-Pathway Status	Serabelisib [1]	Sapanisertib [1]	PIKTOR [1]	Gedatolisib [2]	Alpelisib [1]	Everolimus [1]	Capivasertib [1]	RLY-2608 [1]	STX-478 [1]	Inavolisib [1]	Paclitaxel [1]
MFE-296	PIK3CA-P539R, PTEN-R130Q, MTOR-R1482C	5.17	0.0070	**0.0067**	**0.0158**	0.286	15.4	0.11	3.86	5.92	0.648	0.0088
AN3CA	PTEN-del, PIK3R1-del, MTOR-R1201Q	3.377	0.0108	**0.0050**	**0.0040**	1.653	15.0	0.34	4.85	6.97	1.44	0.0007
HEC1B	PIK3CA-G1049R, RICTOR-D939G	2.346	0.0153	**0.0054**	**0.0500**	0.438	15.2	0.57	8.41	10.5	1.35	0.0042
MFE-280	PIK3CA-H1047	2.19	0.0187	**0.0047**	**0.0520**	1.779	14.8	>100	2.15	1.06	0.113	0.014
MFE-296 Paclitaxel Resistant [2]	PIK3CA-P539R, PTEN-R130Q, MTOR-R1482C	3.521	0.0058	**0.0045**	**ND**	0.438	46.1	0.06	ND	ND	ND	0.035
AN3CA Paclitaxel Resistant [2]	PTEN-del, PIK3R1-del, MTOR-R1201Q	2.671	0.0072	**0.0038**	**ND**	0.494	15.2	0.14	ND	ND	ND	0.015
Endometrial Cancer Average IC50:		3.213	0.0108	**0.0050**	**0.0305**	0.8480	20.28	16.87	4.818	6.113	0.8878	0.0130

PIKTOR achieves pathway suppression at lower concentrations than other PI3K/AKT/mTOR targeted agents

Source: Tyrakis et al., British Journal of Cancer, 2025; 133: 144–154. IC50 values represent the concentration required to achieve 50% reduction in cell number versus control in each cell line. PIKTOR values reflect the sapanisertib IC50 for the combination of serabelisib and sapanisertib at fixed ratio representing clinical exposure. [1] Tyrakis et al., British Journal of Cancer, 2025; 133: 144–154. [2] The Company's internal data. Gedatolisib IC50 values in the endometrial cancer cell lines and data for the paclitaxel-resistant cell line variants are based on the Company's internal preclinical analyses and have not been independently published. ND = not done. Note: When comparing serabelisib and alpelisib, the clinically relevant human exposure for serabelisib is 3-4-fold higher than alpelisib. The IC50 values shown above are derived from in vitro preclinical studies conducted under varying experimental conditions, including differences in cell lines, assay protocols, drug concentrations and combination ratios. No head-to-head preclinical or clinical studies have been conducted among the agents shown. In vitro results may not be predictive of clinical outcomes, and these comparisons should be interpreted with caution.

PK/PD Profile and Phase 2 Dose for Study FTH-PIK-201

Findings from prior development work have led to the characterization of PIKTOR's differentiated pharmacokinetic/pharmacodynamic, or PK/PD, profile and the identification of PIKTOR's phase 2 dose, or RP2D, of 3mg sapanisertib/200mg serabelisib administered on an intermittent dosing schedule of three days per week on a continuous monthly cycle that we are utilizing in our ongoing Phase 2 trial in endometrial cancer, study FTH-PIK-201. We believe this PK/PD-enabled dosage level and frequency combination is important to PIKTOR's potentially differentiated clinical profile because it is designed to maximize the amount of time that plasma concentrations of PIKTOR are at or above in vitro IC90 concentration — potentially as much as two to three times longer per month than competitors — while being within levels that have been generally well tolerated by patients in previous studies.

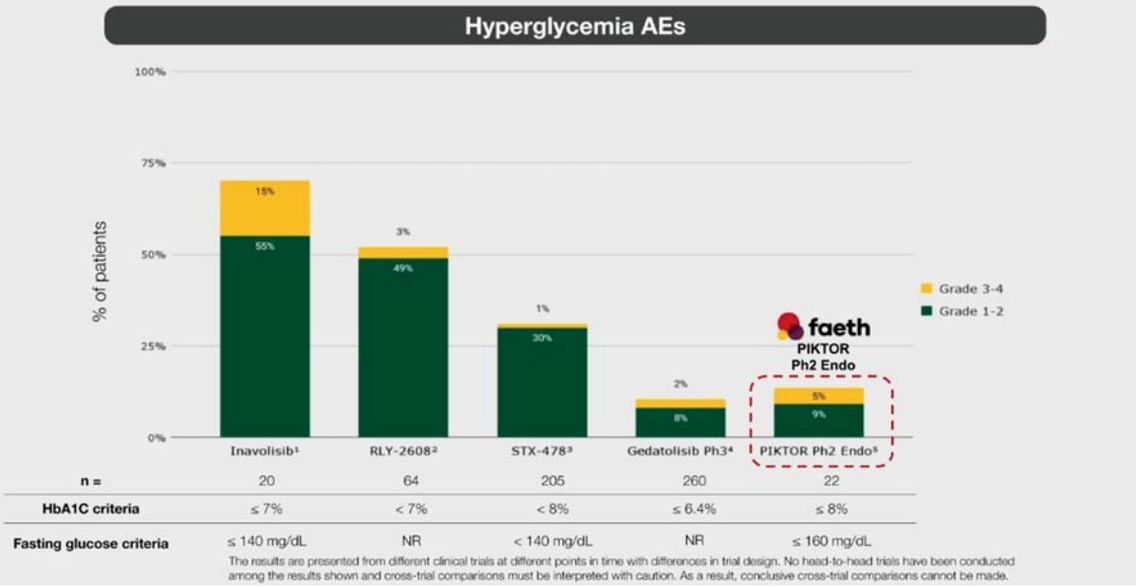


Oral PIKTOR dosing designed to enable sustained exposure and limit risk of potential Cmax-related toxicity

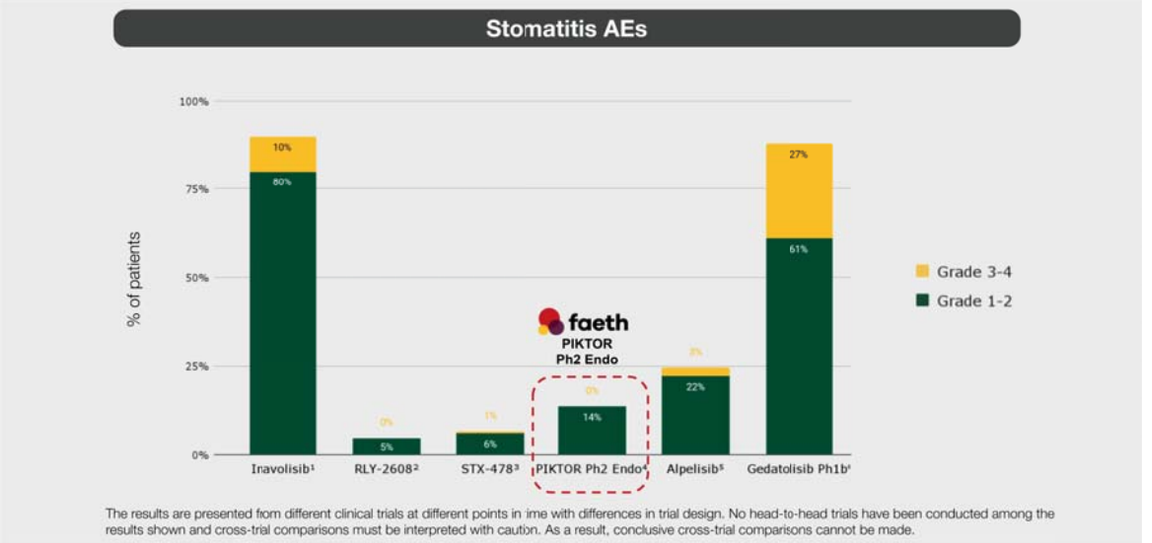
Plot shows ratio of human plasma drug concentration to in vitro (cellular) IC90 for sapanisertib (cellular IC90 determined in HR+ breast cancer cell lines for sapanisertib + serabelisib). Pharmacokinetic (PK) data is modeled from Faeth internal human PK studies and represents Sapanisertib oral capsule 3 mg given once a day with food for 3 days with serabelisib.

Emerging Safety Profile

Beyond the potential efficacy advantages of PIKTOR, we believe clinical data to date suggest a tolerability profile that may compare favorably to both currently approved SNIs and other MNIs in development. The management of treatment-related adverse events, particularly hyperglycemia and stomatitis, has been a meaningful challenge with existing PI3K/AKT/mTOR pathway therapies and has in some cases limited their commercial uptake. Both toxicities have to date been observed at substantially lower rates in our ongoing Phase 2 clinical trial of PIKTOR in advanced endometrial cancer (Study FTH-PIK-201) relative to rates reported in published clinical trials of several other PI3K/AKT/mTOR pathway agents, as depicted below. These comparisons are derived from different clinical trials conducted at different points in time with differences in trial design, including different grading criteria. No head-to-head trials have been conducted among the agents shown, and cross-trial comparisons must be interpreted with caution.



Hyperglycemia Adverse Event rates of selected PI3K pathway compounds



Stomatitis Adverse Event Rates of selected PI3K pathway compounds

Source: Inavolisib: Jhaveri et al. JCO 2024;42(33):3947-3956 (n=20). RLY-2608: ASCO Poster 2025, 600 mg BID, RP2D Cohort (n=64). STX-478: Juric D. et al., ESMO Presentation 2025 (n=205). Gedatolisib (Ph3): Celcuity VIKTORIA-1 Phase 3 Results Presentation, Doublet Arm, Oct 2025 (n=130). PIKTOR Ph2 Endo: Data snapshot, FTH-PIK-201, PIKTOR + Paclitaxel in patients with advanced endometrial cancer, data as of January 5, 2026, ongoing Faeth-sponsored multicenter Phase 2 trial (n=22). Alpelisib: Andre, F. et al., N Engl J Med 2019;380:1929-40 (n=284). Gedatolisib (Ph1b): Layman et al., 2022, SABCS 2022 Poster (n=103).

PIKTOR has several characteristics that we believe may contribute to this emerging tolerability profile. Its PI3Kα isoform specificity may reduce the potential risk of immune compromising toxicities that have been previously associated with pan-PI3K inhibitors. Its oral formulation and intermittent dosing schedule are designed to maintain plasma concentrations within a therapeutic range while avoiding the extreme peak concentrations that may be associated with certain adverse events. In addition, by achieving more complete pathway suppression across multiple nodes, PIKTOR can be administered at substantially lower doses of each component than are required for monotherapy, which we believe may confer deeper efficacy within a more tolerable clinical profile.

Clinical Development History and Evidence to Date

Development History

Both serabelisib and sapanisertib have been studied either alone or in combination, including in combination with other agents, in multiple preclinical studies and in clinical trials involving approximately 1,050 patients at a range of doses. Within the completed studies, 152 patients have received PIKTOR at doses ranging from 2mg to 8mg of sapanisertib and from 100mg to 400mg of serabelisib and in either daily or intermittent schedules in three clinical trials, one of which included both dose escalation and dose expansion cohorts. Across these studies, PIKTOR was generally well tolerated with most AEs considered possibly drug related being mild or moderate in severity. A total of 13 drug-related significant adverse events, or SAEs, all non-fatal, were reported across the three trials. SAEs reported by more than one participant were: increased transaminases (4), nausea (2), vomiting (2), and hyperglycemia (2).

The data that have emerged from these clinical trials — each component demonstrating anti-tumor activity as monotherapy, and the combination generally well tolerated at low doses with clinical activity alongside other agents — support our belief that PIKTOR has the potential to provide more comprehensive and tolerable PI3K/AKT/mTOR pathway inhibition than current SNIs, and may be differentiated from other MNIs in development.

Phase 1b Study X31025 — Results

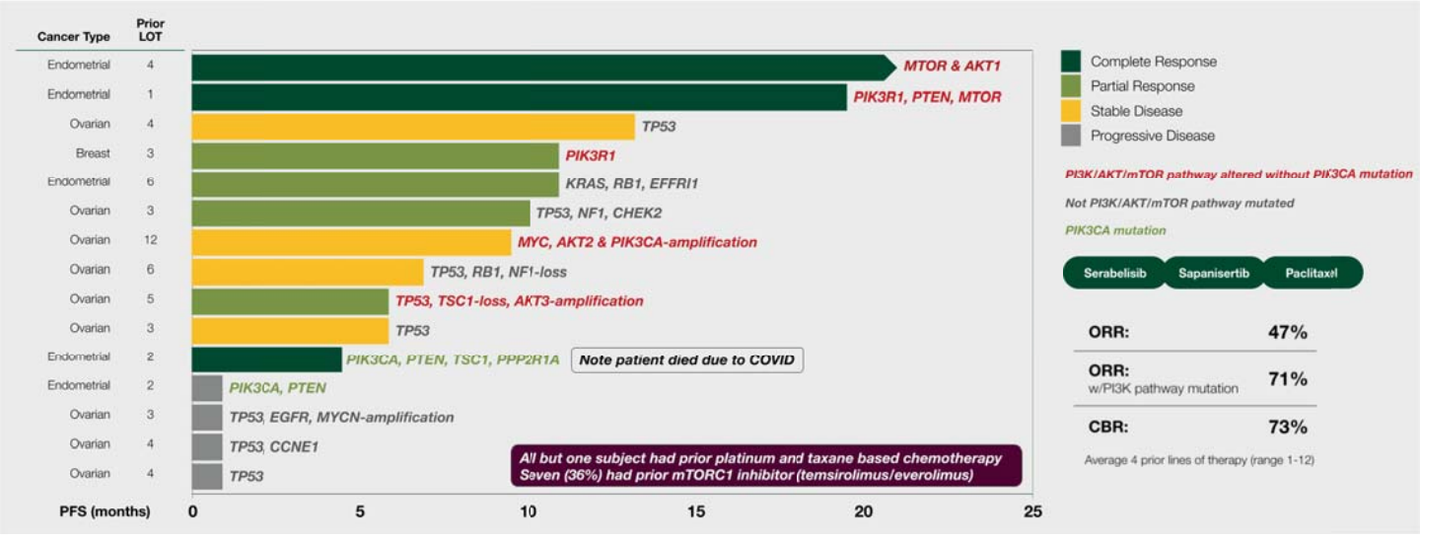
Study X31025 was an investigator-initiated, Phase 1, open-label, single center, dose-escalation trial of PIKTOR in combination with weekly paclitaxel in 19 heavily pretreated patients (averaging four prior lines of therapy) with advanced breast (3), endometrial (6) and ovarian (10) tumors. All but one patient had been previously treated with taxane-based chemotherapy. The study consisted of five dose cohorts which were administered via a three days per week/four weeks per month intermittent dosing schedule. Doses ranged from 2mg to 4mg of sapanisertib, 100mg to 200mg of serabelisib and 60 mg/m² to 80 mg/m² of paclitaxel.

Efficacy Results

At the conclusion of the study, 15 patients were evaluable for efficacy. The objective response rate (ORR) was 47% and the Clinical Benefit Rate, or CBR, was 73%. Amongst patients expressing at least one PI3K/AKT/mTOR pathway mutation, the ORR increased to 71%. Individual patient responses were:

- 3 Complete Responses, or CRs, all in endometrial cancer patients who had failed previous taxane treatment
- 4 Partial Responses, or PRs, 1 breast, 2 ovarian, and 1 endometrial
- 4 Stable Disease, or SD, all ovarian, for greater than or equal to 6 months

At the time of the data cutoff for the publication, median Progression-Free Survival, or PFS, was 11 months, and overall survival, or OS, was 17 months. The genetic profiles of the tumors revealed that 2 patients had direct PI3Kα mutations, 5 had broader PI3K/AKT/mTOR pathway mutations, and 8 had no pathway mutations. Responses were observed across all tumor types and in all mutational classifications.



Patient tumor types, mutations and response status from Phase 1b trial, X31025

Source: Starks DC, Rojas-Espaillat L, Meissner T, Williams CB. Phase I dose escalation study of dual PI3K/mTOR inhibition by Sapanisertib and Serabelisib in combination with paclitaxel in patients with advanced solid tumors. Gynecologic Oncology. 2022 Jul 15. n=19 enrolled (15 response evaluable, 13 RECIST evaluable). Data cutoff per publication October 1, 2021. All but one subject had prior platinum and taxane-based chemotherapy. Seven subjects (36%) had prior mTORC1 inhibitor therapy (temsirolimus/everolimus).
Abbreviations: LOT = Lines of Therapy; ORR = Objective Response Rate; CBR = Clinical Benefit Rate; PFS = Progression-Free Survival.

Tolerability Results

PIKTOR was generally well tolerated in the trial. Most treatment emergent adverse events were classified as mild or moderate and only one dose-limiting toxicity (DLT), which occurred at dose level 5, was observed. The most frequent grade 3 or 4 adverse events were decreased white blood cells, nonfebrile neutropenia, hyperglycemia, anemia, and elevated liver enzymes.

FTH-PIK-201 January 2026 Data Snapshot

PIKTOR's tolerability profile was further informed by the results of a data snapshot we conducted in January 2026 of 22 advanced endometrial cancer patients enrolled in Study FTH-PIK-201. The data showed that PIKTOR continued to be generally well tolerated. Patients experienced stomatitis (13.6% any grade, 0% grade 3/4) and hyperglycemia (13.6% any grade and 4.5% grade 3/4) at levels that compare favorably to existing SNIs and development-stage MNIs. Of note, patients in the PIK-201 study are not required to use any steroid mouthwash prophylaxis.

Clinical Development Plans by Indication

PIKTOR's development is advancing in large, urgent areas of unmet need where dysregulated PI3K/AKT/mTOR pathway activity is strongly implicated in oncogenesis and tumor progression and patients often face a dire prognosis.

Advanced HR+/HER2- Breast Cancer

Disease Overview and Unmet Need

Breast cancer is the most common cancer diagnosed among women in the United States, where it is projected there will be approximately 325,000 new diagnoses in 2026. The most common form of breast cancer is HR+/HER2-, a hormonally driven tumor subtype, which accounts for approximately 70% of overall breast cancer incidence. Amongst total HR+/HER2- cases, approximately 60% express PI3K/AKT/mTOR pathway mutations.

In 2026, an estimated 58,000 HR+/HER2- breast cancer patients are expected to be diagnosed with or progress to advanced disease stages in the United States. For these patients, the current standard of care first-line regimen is endocrine based therapy, either an aromatase inhibitor, or AI, or a SERD in combination with a cyclin-dependent kinase 4/6 (CDK4/6) inhibitor. Together, these agents can slow tumor growth by blocking dysregulated signaling from the hormone receptors on tumors (SERD, AI), as well as the downstream cellular division processes that translate these oncogenic signals into uncontrolled proliferation (CDK4/6). Despite the anti-tumor benefits of this regimen, however, most patients will still experience disease progression within three years from diagnosis, with an expected survival rate at five years of 34%.

Approved SNIs in HR+/HER2- Advanced Disease

Given the strong implication of the PI3K/AKT/mTOR pathway in tumor progression in this setting, the addition of a SNI is recommended for subsequent rounds of endocrine/CDK4/6 therapy following initial progression. There are currently four agents approved for PI3K/AKT/mTOR pathway-altered HR+/HER2- advanced breast cancer, spanning both first- and second-line settings:

First-line (endocrine-resistant, PIK3CA-mutated): Inavolisib (selective PI3Kα inhibitor/degrader), approved in October 2024 in combination with palbociclib and fulvestrant, is the first targeted therapy approved specifically for the first-line treatment of endocrine-resistant, PIK3CA-mutated HR+/HER2- advanced breast cancer. In its pivotal Phase 3 trial, INAVO120, the inavolisib-based triplet more than doubled median PFS compared to palbociclib and fulvestrant alone (15.0 months vs. 7.3 months), reducing the risk of disease progression or death by 57% (HR 0.43). Updated overall survival data have demonstrated a statistically significant survival benefit as well.

Second-line and beyond (post-CDK4/6 progression): Three additional agents are approved for use following progression on CDK4/6 inhibitor-based therapy: alpelisib (selective PI3Kα inhibitor), capivasertib (pan-AKT inhibitor), and everolimus (mTORC1 inhibitor). Of these, the best data generated to date was shown by capivasertib in combination with fulvestrant, a SERD. In its pivotal trial, CAPItello-291, the combination improved median PFS in the PIK3CA/AKT1/PTEN-altered subgroup to 7.3 months vs. 3.1 months for fulvestrant alone, reducing the risk of disease progression or death (hazard ratio) by 50%.

Notably, all four approved agents are single-node inhibitors, each targeting only one component of the PI3K/AKT/mTOR pathway. Three of the four (inavolisib, alpelisib, and capivasertib) also require the presence of specific activating mutations for their approved indications, limiting their addressable patient populations.

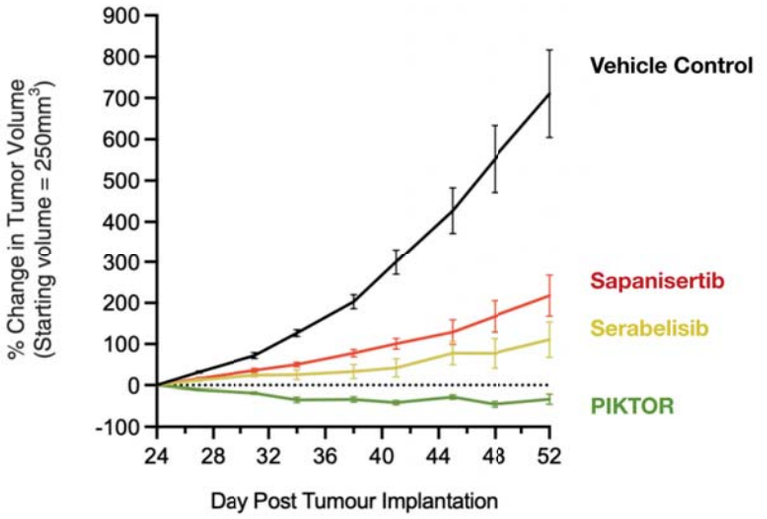
MNI Class Validation via Gedatolisib

Recent clinical trial results from the VIKTORIA-1 trial (PIK3CA-wild-type cohort) of the PI3K/AKT/mTOR pathway MNI gedatolisib (an IV pan PI3K/mTORC1/2 inhibitor) in combination with fulvestrant alone and fulvestrant and palbociclib in combination in advanced HR+/HER2- breast cancer patients with no PIK3CA mutation who are post endocrine therapy/CDK4/6 progression have offered compelling clinical validation for the thesis that an MNI approach can improve outcomes relative to SNIs.

Gedatolisib's results to date have compared favorably relative to the currently approved SNIs, including: PFS of 9.3 months for the gedatolisib triplet (gedatolisib plus fulvestrant plus palbociclib) (HR 0.24) and 7.4 months for the gedatolisib doublet (gedatolisib plus fulvestrant) (HR 0.33) versus fulvestrant alone. Both of these results are superior to any data generated to date in comparable patients by an SNI. We believe these results further validate the superiority of MNI to SNI.

PIKTOR's Development Rationale

Beyond gedatolisib's MNI class-validating results, we believe PIKTOR's substantial body of preclinical evidence demonstrating deep pathway suppression and activity in multiple breast tumor models, including in synergistic combination with palbociclib, provides evidence that PIKTOR has the potential to produce a meaningful benefit to patients in this setting.



PIKTOR's impact on the MDA-MB-361 breast cancer model

Source: Tyrakis et al., British Journal of Cancer, 2025; 133: 144–154 / Faeth Internal Data. Serabelisib dosed at 75 mg/kg (mouse equivalent of 200mg in humans), PO QD, 3 days on / 4 days off. Sapanisertib dosed at 0.5 mg/kg (mouse equivalent of 3mg in humans), PO QD, 3 days on / 4 days off. MDA-MB-361 cell line mutations: PIK3CA, MTOR, BRCA2, BRAF, CDKN2A, TP53. The human-equivalent doses correspond to the RP2D of 200mg serabelisib / 3mg sapanisertib utilized in the Company's ongoing clinical trials.

In addition, results from a Phase 2 clinical trial (Garcia-Saenz et al., 2022) showing that sapanisertib, administered daily and at higher doses than we are contemplating in our future clinical development plans due to tolerability risks, in combination with fulvestrant, could produce comparable results to gedatolisib plus fulvestrant (21.3% Objective Response Rate, or ORR, PFS 7.2 months for sapanisertib plus fulvestrant vs. 28.3% ORR and 7.4 months PFS for gedatolisib plus fulvestrant) in advanced HR+/HER2- breast cancer patients. These are cross-trial comparisons involving different patient populations and trial designs, and should be interpreted with caution.

PIKTOR's Potential for Differentiation Amongst MNIs in HR+/HER2- Breast Cancer

In addition to the general safety and PK/PD profile advantages described in the "Emerging Safety Profile" and "Differentiated Product Profile" sections above, we believe PIKTOR has several characteristics that may combine to create a differentiated profile within the MNI class specifically in the HR+/HER2- breast cancer setting:

- Its oral formulation may enable the establishment of an all oral MNI-based treatment regimen for advanced HR+/HER2- breast cancer that would untether patients from mandatory in-patient infusion treatment
- Low levels of stomatitis at the RP2D — 6% any grade observed in the Phase 1b trial and 13.6% any grade in the January 2026 FTH-PIK-201 data snapshot — that may reduce the need for four times daily prophylactic treatment with a corticosteroid mouthwash
- A PK/PD profile that we believe, based on our analysis of publicly available data, may offer two key advantages over other developmental MNIs: first, PIKTOR's oral intermittent dosing schedule is designed to maintain plasma concentrations at or above the IC90 efficacy threshold for approximately two to three times longer per month; and second, PIKTOR's lower required dose levels result in a substantially lower ratio of peak drug concentration (Cmax) to IC90, which we believe may reduce the risk of concentration-dependent toxicities

Planned Study FTH-PIK-101

Study FTH-PIK-101 is our planned Phase 1b open-label, dose escalation trial of PIKTOR in advanced HR+/HER2- breast cancer. The purpose of this study is to evaluate PIKTOR's safety and preliminary efficacy in combination with fulvestrant, +/- palbociclib, in advanced HR+/HER2- metastatic breast cancer patients who have failed prior systemic therapies.

We expect that the study will evaluate escalating doses of PIKTOR (between 2mg and 4mg of sapanisertib and between 200mg and 300mg of serabelisib) administered three days per week/four weeks per month over 28-day cycles with:

- **Cohort A:** 500mg of fulvestrant alone
- **Cohort B:** 500mg fulvestrant plus 125mg of palbociclib

The Phase 1b component of the study is anticipated to enroll up to six adult participants per dose level in each cohort, up to a total of 36 patients. Pending the successful establishment of the RP2D for each cohort in the Phase 1b portion of the trial, we intend to subsequently enroll at least two expansion cohorts of approximately 30 patients each under a future amendment in Phase 2. We may initiate additional dose escalation cohorts with other investigational agents under a future amendment.

We intend to initiate this trial in the first half of 2026. We anticipate announcing interim data from the dose escalation portion of the trial, and initiating the expansion cohorts, in 2027 and announcing data from the expansion cohorts in 2028.

Advanced Endometrial Cancer

Disease Overview and Unmet Need

Endometrial cancer is the fourth most common cancer in women in the United States, with approximately 62,000 new diagnoses expected in 2026. Between 10,000 and 15,000 women annually will experience advanced disease either at initial diagnosis or due to progression. For these patients, the expected survival rate at five years is 18%.

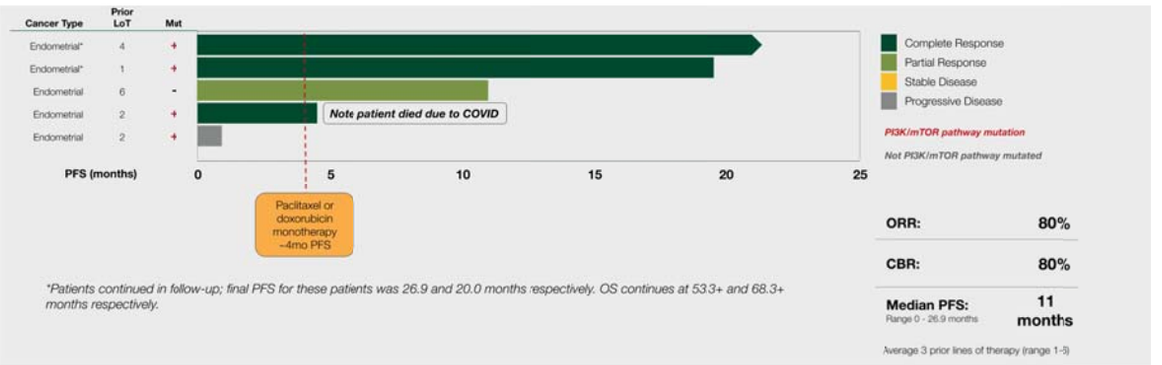
At least one PI3K/AKT/mTOR pathway mutation is present in approximately 80% of endometrial tumors, however, there are currently no approved PI3K/AKT/mTOR pathway inhibitors for endometrial cancer.

Current Treatment Options

The current first-line standard of care regimen for advanced endometrial cancer is chemotherapy, carboplatin plus paclitaxel, combined with an immune checkpoint inhibitor. For patients who progress, second-line treatment consists of pembrolizumab combined with the multi kinase inhibitor lenvatinib, which demonstrated an ORR of 30% with PFS of 6.6 months (HR 0.60) in its pivotal trial, KEYNOTE-775, for which the first-line regimen did not yet include checkpoint inhibitors. If patients cannot tolerate lenvatinib/pembrolizumab or are not expected to respond to a second course of checkpoint inhibitor therapy, the use of single agent chemotherapy, which produced an ORR of 14.7% and PFS of 3.8 months as the control arm in KEYNOTE-775, is recommended.

PIKTOR's Development Rationale

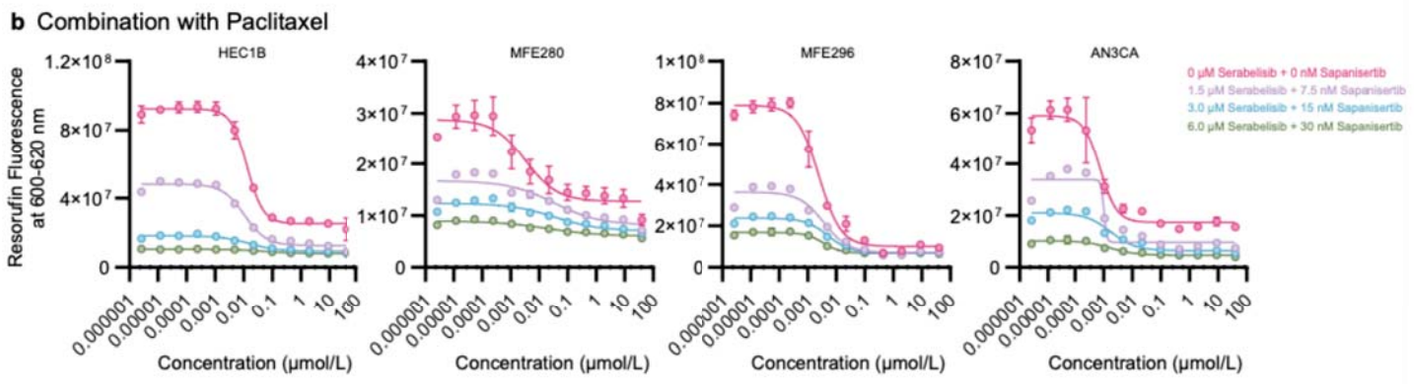
As described in the Phase 1b results above, PIKTOR demonstrated an 80% ORR in five heavily pretreated endometrial cancer patients in Study X31025, including three complete responses, with median PFS of 11 months. We believe these results, combined with preclinical data demonstrating dose dependent inhibitory activity in four endometrial cancer preclinical models (HEC1B, MFE280, MFE296, and AN3CA) in combination with paclitaxel, support our plans to further evaluate PIKTOR in this setting.



Endometrial tumor mutations and response status from Phase 1b trial, X31025

*Source: Starks DC, Rojas-Espaillat L, Meissner T, Williams CB. Phase I dose escalation study of dual PI3K/mTOR inhibition by Sapanisertib and Serabelisib in combination with paclitaxel in patients with advanced solid tumors. Gynecologic Oncology. 2022 Jul 15. Data cutoff per publication October 1, 2021. *Updated follow-up data obtained through unpublished communication with the study investigators. Single-agent chemotherapy reference line (~4 months PFS) represents the approximate median PFS for the chemotherapy control arm (investigator's choice of doxorubicin 60 mg/m² IV every 3 weeks or paclitaxel 80 mg/m² IV weekly, 3 weeks on/1 week off) in the pMMR population of KEYNOTE-775 (Makker et al., NEJM*

2022). Abbreviations: LOT = Lines of Therapy; ORR = Objective Response Rate; CBR = Clinical Benefit Rate; PFS = Progression-Free Survival; OS = Overall Survival.



Preclinical dose-dependent inhibitory activity in endometrial cancer models in combination with paclitaxel

Source: Tyrakis et al., British Journal of Cancer, 2025; 133: 144–154. Cell lines tested: HEC1B, MFE280, MFE296, AN3CA. Dose-response curves: Serabelisib dosed at 0 - 6uM, sapanisertib dosed at 0 - 30nM, paclitaxel dosed within the range 0.001nmol/L-100umol/L. Cells exposed to drugs for 3 days (72 hours). Resorufin Fluorescence at 600-620 nm used to quantify cell number. PI3K-pathway mutation status of the cell lines is shown in the IC50 table above.

Based on these results, we believe PIKTOR may offer improved outcomes for second-line advanced endometrial cancer patients.

We also see a potential first-line opportunity for PIKTOR in the genetically defined subpopulation of patients whose tumors are classified as mismatch repair proficient, or MMR-p. These patients constitute approximately 70% of the overall advanced endometrial cancer population and their tumors have been shown to respond less favorably to immune therapy in multiple trials across tumor types than patients whose tumors are classified as mismatch repair deficient, or MMR-d.

Study FTH-PIK-201

Study FTH-PIK-201 is our ongoing single arm Phase 2 study of 3mg/200mg of PIKTOR (3 days a week) in combination with 80 mg/m² of paclitaxel (weekly) in endometrial cancer. The study consists of 40 endometrial cancer patients with a confirmed PI3K/AKT/mTOR pathway mutation who have previously been treated with checkpoint inhibitors and carboplatin. There is also an optional sub-study available to enrollees to combine an insulin suppressing diet with their treatment.

The primary endpoint of the trial is ORR with key secondary endpoints: PFS, OS, CBR, Duration of Response, or DOR, and safety/tolerability.

We have initiated this Phase 2 trial, with topline data currently anticipated by year-end 2026. We anticipate dosing the last patient in this trial and announcing longer term follow-up data in 2027.

Potential Future Indications

Beyond advanced HR+/HER2- breast cancer and advanced endometrial cancer, we may also consider developing PIKTOR in additional indications where there are large unmet needs, PI3K/AKT/mTOR pathway activity is implicated in disease progression, and PIKTOR or its components have displayed clinical activity.

Our potential interest in ovarian cancer is driven by encouraging activity in the ovarian patients in the investigator-initiated Phase 1b trial (Study X31025), described above, as well as the results of the Phase 2 “DICE” trial. The DICE trial was a randomized controlled investigator-initiated trial of 134 ovarian cancer patients designed to evaluate the addition of 4 mg of sapanisertib in combination with 80 mg/m² of paclitaxel versus 80 mg/m² of paclitaxel alone. The results of the trial, which were presented as a late-breaking oral presentation at the annual meeting of the European Society for Medical Oncology, or ESMO, in 2025, met the trial's pre-specified primary endpoint. Addition of sapanisertib to paclitaxel was associated with a 34% decrease in risk of disease progression (HR=0.66; pre-specified 90% CI: 0.45–0.96; one-sided p=0.07). Mean PFS was 5.8 months for patients treated with sapanisertib and paclitaxel versus 4.0 months for patients treated with paclitaxel alone. The combination of sapanisertib and paclitaxel was generally well tolerated, with Grade 3/4 adverse events occurring in 7% of patients in the combination arm compared to 6.6% of patients in the paclitaxel monotherapy arm.

PIKTOR has also demonstrated clinical activity in certain genetically defined subtypes of lung cancer. Depending on discussions with regulatory authorities, we intend to explore the possibility of initiating future clinical trials of PIKTOR in this setting.

We have not yet initiated an independent clinical trial of PIKTOR in either ovarian cancer or lung cancer, and any future development in these settings will depend on further discussions with regulatory authorities and the results of our ongoing trials in our lead indications.

Other Pipeline Programs

Faeth Pipeline Programs

We have created a multi-asset development portfolio utilizing our expertise in cancer biology and metabolic disease to generate compelling pipeline assets by identifying additional opportunities to address significant unmet needs. Our platform seeks to identify and exploit potential cancer cell vulnerabilities to create integrated treatment regimens to deny tumors the signaling pathways and nutrients they depend upon to proliferate.

NEAAR (Non Essential Amino Acid Restriction)

We call our second pipeline program NEAAR. This regimen restricts patient intake of specific non-essential amino acids that we have determined tumors use to support proliferation. NEAAR has demonstrated pre-clinically that, by itself, it can suppress tumor growth and increase survival, and in combination, can increase the sensitivity of cancer cells to chemotherapies, radiotherapy and targeted therapies.

IEM (Inborn Errors of Metabolism)

Our broad understanding of metabolic disease has enabled our third program, IEM, which may improve treatment options for a rare inherited metabolic disease, Type I Tyrosinemia, by eliminating an off-target effect of the current standard of care drug that we believe may cause neurocognitive impairment. In preclinical models, our IEM program has shown equivalence to current standard of care in rescuing underlying disease pathology while maintaining normal neurocognitive function.

Sensei Legacy Programs

In addition to PIKTOR and the Faeth pipeline programs described above, our pipeline includes programs that preceded the Acquisition. We are completing a Phase 1/2 trial of solnerstotug (formerly SNS-101), our conditionally active monoclonal antibody targeting the immune checkpoint VISTA. As of March 23, 2026, seven patients remain on study in the expansion portion of the trial. We also have three preclinical-stage conditionally active antibody programs: SNS-102 (targeting VSIG4), SNS-103 (targeting CD39), and SNS-201, a bispecific antibody designed to conditionally activate CD28 through monovalent CD28 engagement and bivalent pH-selective VISTA binding.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. While we believe our deep scientific knowledge of oncology paired with our differentiated lead product candidate, PIKTOR, provides a strong competitive advantage, we face competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions.

Our competitors may have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. They may also compete in recruiting and retaining qualified scientific, sales, marketing and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to or necessary for our product candidates. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity can be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Competitors also may obtain U.S. Food and Drug Administration, or FDA, or other regulatory approval for their products more rapidly or earlier than us, which could result in our competitors establishing a strong market position before we are able to enter

the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing our product candidates against competitors.

PI3K/AKT/mTOR Competitive Landscape

In addition to the five approved SNI agents described above, our comprehensive search of available resources and databases revealed there are several additional product candidates in clinical development which could pose a direct competitive threat to PIKTOR, particularly for the treatment of advanced HR+/HER2- breast cancer. These product candidates include:

- **Pan-PI3K/mTOR Inhibitors**
  - **Gedatolisib**, an IV pan-PI3K/mTOR inhibitor from Celcuity, whose New Drug Application for HR+/HER2-, PIK3CA wild-type metastatic breast cancer was accepted by the FDA in January 2026 with Priority Review and a Prescription Drug User Fee Act goal date of July 17, 2026. Gedatolisib's clinical efficacy data is discussed in the context of MNI class validation in the breast cancer development section above.
  - **Paxalisib**, an oral brain penetrant pan-PI3K/mTOR inhibitor from Kazia Therapeutics, currently in Phase 3 trials in glioblastoma.
- **Mutant-PI3Kα Inhibitors**
  - **Zovegalisib**, an oral inhibitor of mutant PI3Kα from Relay Therapeutics, currently in Phase 3 trials for advanced HR+/HER2- breast cancer.
  - **Tersolisib**, an oral inhibitor of mutant PI3Kα from Eli Lilly, currently in Phase 3 trials for HR+/HER2- breast cancer.
  - **SNV4818**, an oral inhibitor of mutant PI3Kα acquired by Novartis from Synnovation Therapeutics in March 2026, currently in Phase 1/2 trials for HR+/HER2- breast cancer and other advanced solid tumors.
  - **OKI-219**, an oral inhibitor of mutant PI3Kα from OnKure Therapeutics, currently in Phase 1a/1b trials for HR+/HER2- metastatic breast cancer and other advanced solid tumors as monotherapy, in combination with fulvestrant, and in triplet combinations with fulvestrant/ribociclib and trastuzumab/tucatinib.
- **AKT Inhibitor**
  - **Afuresertib**, an oral pan AKT inhibitor from Laekna Therapeutics, currently in Phase 3 trials for advanced HR+/HER2- breast cancer.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We will also seek to rely on regulatory protection afforded through inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available.

Wherever possible, we pursue claims directed to the clinical product or product candidates. Such applications may not result in issued patents and, even if patents do issue, such patents may not be in a form that will provide us with meaningful protection for our product. We also rely on trade secrets that may be important to the development of our business. Trade secrets are difficult to protect and provide us with only limited protection.

PIKTOR

We hold our rights to serabelisib and sapanisertib under exclusive license and asset purchase agreements with Takeda Pharmaceutical Company Limited, or Takeda, and its subsidiary Millennium Pharmaceuticals, Inc., or Millennium Takeda, as described in the "Material Agreements" section below. We are actively building our intellectual property portfolio around PIKTOR to protect the composition of matter of both serabelisib and sapanisertib as well as for its method of use in the types of cancer in which we intend to develop it. Our patent portfolio for PIKTOR, as of March 23, 2026, contains 13 issued U.S. patents, four pending U.S. applications, and three pending patent cooperation treaty applications that are either solely owned by us or in-licensed, as well as certain foreign counterparts of a subset of these patent applications in foreign countries, including in Algeria, Australia, Brazil, Canada, Chile, China, Colombia, Europe, Eurasia, Georgia, Hong Kong, India, Indonesia, Israel, Japan, Kazakhstan, Macao, Malaysia, Mexico, Morocco, New Zealand, Nigeria, Peru, Philippines, Russia, Singapore, South Africa, South Korea, Tunisia,

Ukraine, Uzbekistan, and Vietnam. For PIKTOR, these patents and patent applications are directed to compositions, methods of manufacturing, and methods of treating cancer. If issued, the 20-year term expiration dates from which our patents will expire are between 2027 and 2046, not including any extension of the patent term that may be available in certain jurisdictions. We continue to seek to maximize the scope of our patent protection for PIKTOR.

Sensei Legacy Programs

Prior to the Acquisition, we developed a portfolio of intellectual property relating to our TMAb conditionally active biologic platform and product candidates. As of March 23, 2026, our solely owned legacy patent estate included one issued U.S. patent, one pending U.S. patent application, and nine international patent applications. We also co-own five pending U.S. patent applications and five pending international patent applications.

We own one U.S. non-provisional and eight international patent applications relating to composition of matter of our solnerstotug product candidate and method claims including use in combination with immune checkpoint protein inhibitors. Subject to payment of required maintenance fees, annuities, and other charges, any patents, if issued, are projected to expire in 2042.

Takeda License Agreement

We are party to a license agreement with Takeda that was originally entered into in March 2019, or the Takeda License Agreement, between Takeda and Petra Pharma Corporation, or Petra, which was subsequently assigned by Petra to Ravenna Pharmaceuticals, Inc., or Ravenna, and later acquired by Faeth in February 2021 in connection with its acquisition of assets related to serabelisib pursuant to an asset purchase agreement with Ravenna.

Under the Takeda License Agreement, we are granted an exclusive, royalty-bearing license, with the right to grant sublicenses, under certain patents and know-how controlled by Takeda to research, develop, make, have made, import, export, use, have used, sell, have sold, offer for sale, or otherwise dispose of and commercialize serabelisib and certain back-up compounds, and analogs, derivatives, fragments or modifications that we obtain from serabelisib or such back-up compounds, or, collectively, the Serabelisib Compounds, and products comprising Serabelisib Compounds, or Serabelisib Products, for all human therapeutic uses excluding certain non-oncology indications, or the Serabelisib Field, throughout the world.

We are solely responsible, at our cost, for the development, manufacture, and commercialization of the Serabelisib Compounds and Serabelisib Products in the Serabelisib Field. We are obligated to use commercially reasonable efforts to develop and commercialize at least one Serabelisib Product.

We are obligated to pay Takeda tiered single-digit royalties on annual net sales of Serabelisib Products (except for PIKTOR Products, the royalties for which are set forth in the Takeda Letter Agreements described below). The royalty payments are subject to reduction under certain customary circumstances. On a Serabelisib Product-by-Serabelisib Product and country-by-country basis, our royalty payment obligations commence on the first commercial sale of such Serabelisib Product in the applicable country until the latest to occur of (a) the last-to-expire valid claim within the licensed patents covering such Serabelisib Product in the applicable country, (b) the expiration of any applicable regulatory exclusivity for such Serabelisib Product in the applicable country and (c) ten (10) years after the first commercial sale of such Serabelisib Product in the applicable country. We are obligated to pay Takeda development, regulatory and sales milestone payments for Serabelisib Products under the Takeda Letter Agreements, as described below.

The Takeda License Agreement will remain in effect on a Serabelisib Product-by-Serabelisib Product and country-by-country basis until expiration of all royalty payment obligations, unless earlier terminated. Following expiration, the licenses granted to us become fully-paid, royalty-free, irrevocable and perpetual.

Either party may terminate the Takeda License Agreement in whole or, to the extent applicable to the subject matter of the breach, on a Serabelisib Product-by-Serabelisib Product or country-by-country basis, in the event of the other party's uncured material breach. Either party may also terminate the Takeda License Agreement in its entirety in connection with the other party's insolvency. Takeda may terminate the Takeda License Agreement if we challenge a licensed patent.

If we abandon development and commercialization of all Serabelisib Compounds and Serabelisib Products, Takeda has the right to terminate the Takeda License Agreement and assume development and commercialization responsibilities for the Serabelisib Compounds and Serabelisib Products. If Takeda elects to take over development and commercialization responsibilities, we are required to engage in good faith discussions to grant Takeda a license under certain patents and know-how that we control that are related to the Serabelisib Products or necessary or useful for the exploitation of the Serabelisib Products, but we are not obligated to grant such a license.

Amended and Restated Asset Purchase Agreement with Millennium Takeda

We are party to an amended and restated asset purchase agreement with Millennium Takeda that was originally entered into in May 2023, or the Millennium Takeda Asset Purchase Agreement, between Millennium Takeda and Calithera Biosciences, Inc., or Calithera, which was acquired by Faeth in May 2023 in connection with its acquisition of assets related to sapanisertib pursuant to an asset purchase agreement with Calithera.

Pursuant to the Millennium Takeda Asset Purchase Agreement, Millennium Takeda assigned to Calithera certain know-how and certain patents and patent applications, or the Assigned Patent Rights, related to sapanisertib that Faeth subsequently acquired from Calithera in May 2023 under the asset purchase agreement. Under the Millennium Takeda Asset Purchase Agreement, we are also granted a non-exclusive license, with the right to grant sublicenses, under certain patent rights and know-how controlled by Millennium Takeda to research, develop, make, have made, use and import sapanisertib, compounds that are disclosed or claimed in any Assigned Patent Right that also discloses sapanisertib and certain other pharmaceutical forms of sapanisertib or such compounds, or, collectively, the Sapanisertib Program Molecules, and to research, develop, make, have made, use, sell, offer for sale, and import products containing or comprising Sapanisertib Program Molecules, or the Sapanisertib Products, in any therapeutic, prophylactic, preventative or diagnostic use in or for animals, including humans, or the Sapanisertib Field, throughout the world.

We are obligated to use commercially reasonable efforts to research and develop, including to obtain regulatory approval for, and upon obtaining regulatory approval to commercialize at least one Sapanisertib Product in each of the United States, Japan and at least three countries selected from United Kingdom, Germany, France, Spain and Italy.

We are obligated to pay Millennium Takeda tiered high single-digit to low double-digit royalties on annual net sales of all Sapanisertib Products (except for PIKTOR Products, the royalties for which are set forth in the Takeda Letter Agreements described below). On a Sapanisertib Product-by-Sapanisertib Product and country-by-country basis, our obligation to pay Millennium Takeda royalties commences on the first commercial sale of such Sapanisertib Product in the applicable country until the latest to occur of (a) the last-to-expire valid claim within the Assigned Patents and licensed patents covering such Sapanisertib Product in the applicable country, (b) the expiration of any applicable regulatory exclusivity for such Sapanisertib Product in the applicable country and (c) ten (10) years after the first commercial sale of such Sapanisertib Product in the applicable country. The royalty payments are subject to reduction under certain customary circumstances. Upon expiration of our royalty payment obligations with respect to a Sapanisertib Product and a country, the license granted to us for such Sapanisertib Product in such country will become fully-paid, perpetual, and irrevocable. We are also obligated to pay Takeda development, regulatory and sales milestone payments for Sapanisertib Products under the Takeda Letter Agreements described below.

The Millennium Takeda Asset Purchase Agreement will remain in effect until expiration of our obligations to make royalty payments to Takeda, unless earlier terminated. Either party may terminate the Millennium Takeda Asset Purchase Agreement in connection with the other party's uncured material breach or insolvency. Upon termination of the Millennium Takeda Asset Purchase Agreement, all licenses granted by Millennium Takeda to us automatically terminate. Upon Millennium Takeda's request after termination, we are required to assign to Millennium Takeda the acquired assets and certain intellectual property generated in the performance of the agreement that solely relate to, or were used by us or on our behalf, Sapanisertib Program Molecules and Sapanisertib Products and all regulatory materials that are needed to continue fully exploiting Sapanisertib Program Molecules and Sapanisertib Products.

Letter Agreements with Takeda and Millennium Takeda

We are party to a letter agreement with Millennium Takeda that was entered into in May 2023, or the First Takeda Letter Agreement, to amend the Millennium Takeda Asset Purchase Agreement and to a letter agreement with Takeda and Millennium Takeda that was entered into in January 2026, or the Second Takeda Letter Agreement, to amend the Takeda License Agreement, the Millennium Takeda Asset Purchase Agreement, and the First Takeda Letter Agreement. The First Takeda Letter Agreement and the Second Takeda Letter Agreement are referred to collectively as the "Takeda Letter Agreements."

Pursuant to the Takeda Letter Agreements, we are obligated to pay Takeda and Millennium Takeda up to an aggregate of $119.0 million in development, regulatory, and commercial launch milestone payments and up to an aggregate of $250.0 million in sales milestone payments for PIKTOR and any other products that contain both a Serabelisib Compound and a Sapanisertib Program Molecule as the only active ingredients, or collectively PIKTOR Products, Serabelisib Products, and Sapanisertib Products.

We are also obligated to pay Takeda and Millennium Takeda tiered single-digit royalties on annual net sales of PIKTOR Products. On a PIKTOR Product-by-PIKTOR Product and country-by-country basis, our obligation to pay royalties commences on the first commercial sale of such PIKTOR Product in the applicable country and continues until the latest to occur of (a) the last-to-expire valid claim within the Assigned Patents under the Millennium Takeda Asset Purchase Agreement or the licensed patents under the Millennium Takeda Asset Purchase Agreement or the Takeda License Agreement, in each case, covering such PIKTOR Product in the applicable country, (b) the expiration of any regulatory exclusivity for such PIKTOR Product in the applicable country and (c) ten (10) years after the first commercial sale of such PIKTOR Product in the applicable country. The royalty payments for PIKTOR Products are subject to reduction under certain customary circumstances.

The Second Takeda Letter Agreement specifies that PIKTOR Products are considered Serabelisib Products under the Takeda License Agreement and Sapanisertib Products under the Millennium Takeda Asset Purchase Agreement. The Second Takeda Letter Agreement also amends the Takeda License Agreement and the Millennium Takeda Asset Purchase Agreement to add certain specific IND-related materials for PIKTOR Products controlled by Takeda or Millennium Takeda to the know-how licensed to us under those agreements.

University of California License Agreement

We are party to an exclusive license agreement with The Regents of the University of California, or The Regents, that was originally entered into in August 2007 between The Regents and Intellikine, Inc., or Intellikine, and amended in March 2009, July 2009, November 2010, September 2014, August 2021 and February 2022, or the UC License Agreement, which was subsequently assigned by Intellikine to Millennium Takeda, which was subsequently assigned by Millennium Takeda to Calithera and later acquired by Faeth Therapeutics in May 2023 in connection with its acquisition of assets related to sapanisertib pursuant to its asset purchase agreement with Calithera.

Under the UC License Agreement, we are granted a license, with the right to grant sublicenses, to make, have made, use, sell, offer for sale and import (a) products that are covered by the claims of certain patent rights controlled by The Regents, or the UC Licensed Products, or that are produced by methods covered by such patent rights, or the UC Licensed Methods, and services that involve UC Licensed Products or UC Licensed Methods or that involve certain materials or know-how controlled by The Regents, or the UC Licensed Services, and (b) to practice the UC Licensed Methods, in each case, (a) and (b), in the United States and all other countries where The Regents may grant such licenses, or the UC Licensed Territory, for all fields and all uses, or the UC Licensed Field. The license granted to us is exclusive with respect to such patent rights and is non-exclusive with respect to such know-how.

We are obligated to proceed diligently with the development, manufacture, and sale of UC Licensed Products and UC Licensed Services and earnestly and diligently to market UC Licensed Products and UC Licensed Services in quantities intended to be sufficient to meet market demand. We are also required to meet specific development diligence timelines for certain UC Licensed Products, which may be extended subject to payment of an extension fee. If we fail to meet, subject to a cure period, or extend such timelines, The Regents have the right to terminate the UC License Agreement or to convert the licenses to a non-exclusive basis with respect to the relevant UC Licensed Products.

We are required to pay The Regents an annual license maintenance fee of $25,000 until we begin paying royalties under the UC License Agreement. We are also required to pay The Regents a low double-digit percentage of income that we receive from our sublicensees if we sublicense the rights granted to us under the UC License Agreement. We are also obligated to pay The Regents tiered low single-digit royalties based on cumulative net sales of UC Licensed Products, UC Licensed Services and UC Licensed Methods. Beginning with the year of the first commercial sale of the UC Licensed Product and continuing until expiration of all licensed patent rights, we are required to pay The Regents a minimum annual royalty of $25,000, which will be credited against the royalties owed to The Regents. The royalty payments owed to The Regents are subject to reduction under certain customary circumstances. On a UC Licensed Product-by-UC Licensed Product, UC Licensed Service-by-UC Licensed Service, UC Licensed Method-by-UC Licensed Method and country-by-country basis, our obligation to pay royalties commences on the first commercial sale of such UC Licensed Product, UC Licensed Service, or UC Licensed Method, as applicable, in the relevant country and continues until expiration of the last-to-expire valid claim within the licensed patent rights that covers such UC Licensed Product, UC Licensed Service, or UC Licensed Method, as applicable, in the relevant country. We are also obligated to pay The Regents up to $800,000 in development and regulatory milestones payments for certain UC Licensed Products.

The UC License Agreement will remain in effect until expiration or abandonment of the licensed patents. The UC License Agreement will automatically terminate in connection with our insolvency. The Regents have the right to terminate the UC License Agreement in its entirety or with respect to specific licensed patents based on our uncured material breach. We have the right to terminate the UC License Agreement in its entirety or with respect to specific licensed patents on a country-by-country basis, upon advance written notice to The Regents.

Adimab Agreement

On July 14, 2021, we entered into a First Amended and Restated Collaboration Agreement, or the Adimab Agreement, with Adimab, LLC, or Adimab. Under the Adimab Agreement, we selected a number of biological targets against which Adimab used its proprietary platform technology to discover and/or optimize antibodies based upon mutually agreed upon research plans, and we have the ability to select a specified number of additional biological targets against which Adimab will provide additional antibody discovery and optimization services. During the research term and evaluation term for a given research program with Adimab, or Research Program, we have a non-exclusive worldwide license under Adimab's technology to perform certain research activities and to evaluate the program antibodies to determine whether we want to exercise our option to obtain an exclusive license to exploit such antibodies, referred to herein as a "Development and Commercialization Option."

Pursuant to the Adimab Agreement, we previously paid Adimab a one-time, non-creditable, non-refundable technology access fee of $50,000. We are also obligated to make certain technical milestone payments to Adimab for each Research Program up to $275,000. Upon exercise of a Development and Commercialization Option, we are obligated to pay to Adimab a non-creditable, nonrefundable option exercise fee of $500,000 plus an amount equal to any technical milestone payment which was not previously paid with respect to such Research Program and less any option extension fees paid with respect to such Research Program. On a product-by-product basis, we will pay Adimab upon the achievement of various clinical and regulatory milestone events with total milestone payments up to an aggregate of $13.3 million for the first product from a Research Program and up to an aggregate of $6.6 million for each subsequent product from a Research Program. For any product that is commercialized, on a country-by-country and product-by-product basis, we are obligated to pay to Adimab a low-to-mid single-digit percentage of annual worldwide net sales of such product during the applicable royalty period in each country.

Solnerstotug is subject to the terms of the Adimab Agreement, and in December 2022 we exercised our Development and Commercialization Option for the Research Program from which solnerstotug was generated. To date, we have paid $1,875,000 to Adimab pursuant to the Adimab Agreement for the technology access fee, Development and Commercialization Option, program delivery fees and a milestone payment for the first patient dosed in our Phase 1/2 clinical trial of solnerstotug.

General

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed 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 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 expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any issued patents we may obtain in any jurisdiction where such patent term extensions are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

We expect to file additional patent applications in support of current and new clinical candidates as well as new platform and core technologies. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors—Risks Related to Our Intellectual Property."

We maintain a portfolio of registered and pending trademarks to protect our brand identity. In addition to patent and trademark protection, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees, and consultants. These and other agreements, such as invention assignment agreements, grant us ownership of technologies that are developed through a relationship with a third party. 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. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Chemistry, Manufacturing, and Controls

We believe the quality and amount of the current sapanisertib and serabelisib drug supply (DS) and drug product (DP) is appropriate for our current and expected clinical trials. Further CMC development is ongoing, including activities leading to the manufacture of batches in support of potential future registrational trials, New Drug Application, or NDA, submissions, and required regulatory validation of DS/DP manufacturing processes in anticipation of any potential commercial launch.

Commercial Opportunity

We believe the commercial potential for PIKTOR, if approved, in advanced HR+/HER2- breast cancer and endometrial cancer is substantial given the prevalence of the conditions, the urgency of the unmet medical need and the potential breadth of PIKTOR's benefit across these substantial patient populations. In the United States alone, we believe the total addressable market for our currently targeted indications, second-line HR+/HER2- breast cancer and second-line advanced endometrial cancer, is approximately $6 billion based on our analysis of the patient populations and current pricing paradigms for these treatment settings, as of 2026, as well as third party estimates of these markets and the publicly disclosed sales totals achieved by currently available treatments for these settings. Within this overall total, HR+/HER2- breast cancer accounts for approximately $5 billion and advanced endometrial cancer the remaining $1 billion. Given our stage of development, however, we have not yet established either a commercial organization or distribution capabilities.

Government Regulation

Government authorities in the United States, at the federal, state and local level and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the New Drug Application, or NDA, process before it may be legally marketed in the United States.

U.S. Drug Development Process

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

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

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the

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

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

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

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

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition, and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance and appropriate dosage.
- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

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

FDA Regulatory Framework for Fixed-Combination Prescription Drugs for Humans

The FDA's regulation at 21 CFR § 300.50 governing fixed-combination drug products provides, among other things, that two or more drugs may be combined in a single dosage form when each component contributes to the claimed effects and the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the drug. This rule is meant to ensure that any fixed-dose combination drug provides an advantage to the patient over and above that obtained when one of the individual ingredients is used in the usual safe and effective dose.

U.S. Review and Approval Process

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

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

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP regulations.

After the FDA evaluates an NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as additional clinical trials or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the NDA addressing all of the deficiencies identified in the letter or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct "Phase 4" testing, which involves clinical trials designed to further assess a drug's safety and/or effectiveness following NDA approval, and may require additional testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products.

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

clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Expedited Development and Review Programs

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

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

Any product candidate submitted to the FDA for approval, including a product candidate with a fast track designation or breakthrough designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. An NDA is eligible for priority review if the product candidate is designed to treat a serious condition and, if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of a NDA designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

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

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

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections

by the FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP regulations and other aspects of regulatory compliance.

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

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

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

Hatch-Waxman Act

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application 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 a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, 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, or the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. If the Paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the Paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the Paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a Paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

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

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of existing exclusivity or an available patent term if a sponsor conducts clinical trials in children in response to a "written request" from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials, and the FDA's grant of pediatric exclusivity does not require the FDA to approve labeling containing information on pediatric use based on the studies conducted.

Other U.S. Healthcare Laws

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including but not limited to the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, or HHS, the Department of Justice, the Drug Enforcement Administration, and state and local governments.

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose

pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, or FCA, which may constrain the business or financial arrangements and relationships through which companies sell, market and distribute pharmaceutical products. In addition, transparency laws and patient privacy regulations by federal and state governments and by governments in foreign jurisdictions can apply to the manufacturing, sales, promotion and other activities of pharmaceutical manufacturers. The applicable federal, state and foreign healthcare laws and regulations that can affect a pharmaceutical company's operations include:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs, or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of an applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal 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 relevant facts and circumstances.

- The federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement, including providing inaccurate billing or coding information to customers or promoting a product off-label, material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the federal government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- The anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of items or services reimbursable, whole or in part, by a federal or state governmental program;

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, 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 statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their subcontractors that use, disclose or otherwise process individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- The federal legislation commonly referred to as the Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, and its implementing regulations, which requires manufacturers of drugs, devices, biologics and medical supplies for which

payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professions (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members;

- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- Analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring certain regulatory licenses to manufacture or distribute products commercially and/or the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act.

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

Violations of the aforementioned laws can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight under a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Additionally, private individuals have the ability to bring actions on behalf of the U.S. government under the federal FCA as well as under the false claims laws of several states against a pharmaceutical manufacturer. The approval and commercialization of a pharmaceutical manufacturer's product candidates outside the United States will also likely subject it to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Lastly, 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 criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical company to incur significant legal expenses and divert management's attention from the operation of the business.

U.S. Healthcare Reform

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry.

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

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

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives which could limit the amounts that federal and state governments will pay for healthcare products and services and result in reduced demand for certain pharmaceutical products or additional pricing pressures.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional foreign, federal and state healthcare reform measures will be adopted in the future.

U.S. Patent-Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of our drug candidates, if any, some 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, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, or the testing phase, plus the time between the submission date of an NDA and the approval of that application, or the approval phase. This patent term restoration period may be reduced by the FDA if it finds that applicant did not act with due diligence during the testing phase or the approval phase. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, if circumstances permit, we intend to apply for restoration of patent term for one of our then owned or licensed patents, if any, to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA. Even if, at the relevant time, we have a valid issued patent covering our product, we may not be granted an extension if we were, for example, to fail to apply within applicable deadlines, to fail to apply prior to expiration of relevant patents or otherwise to fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, and we do not have any other exclusivity, our competitors may obtain approval of competing products following our patent expiration and our ability to generate revenues could be materially adversely affected.

Some of our products may also be entitled to certain non-patent-related data exclusivity under the FDCA. The FDCA provides a five-year period of non-patent data exclusivity within the U.S. to the first applicant to obtain approval of an NDA for a new chemical entity ("NCE"). A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, an abbreviated new drug application ("ANDA"), or a 505(b)(2) NDA may not be submitted by another company for another drug containing the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA Orange Book by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for a full NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. Three-year exclusivity prevents the FDA from approving ANDAs and 505(b)(2) applications that rely on the information that served as the basis of granting three-year exclusivity. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations, and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Certain additional periods of exclusivity may be available if a product is indicated for use in a rare disease or condition or is studied for pediatric indications. 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 product exclusivity, which the FDA has interpreted to preclude approving for seven years any other sponsor's application to market the same drug for the same use for which the drug has been granted orphan drug designation, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Orphan exclusivity operates independently from other regulatory exclusivities and other protection against generic competition, including patents that we hold for our products. A sponsor of a product application that has received an orphan drug designation may also be granted tax incentives for clinical research undertaken to support the application.

Orphan drug exclusivity does not block approval of competing products intended for the orphan-protected indication but containing a different active moiety, or containing the same moiety but intended for a different use. Orphan product exclusivity that could block a competitor to one of our products also could block the approval of one of our products for seven years if a competitor obtains approval of the product containing the same moiety for the same orphan disease or condition.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. The FDASIA made permanent the Best Pharmaceuticals for Children Act, or BPCA, which extends any existing regulatory exclusivity and patent periods by an additional six months if the sponsor conducts clinical trials in children in response to a Written Request from the FDA. If the Written Request does not include studies in neonates, the FDA is required to include its rationale for not requesting those studies. The FDA may request studies on approved or unapproved indications in separate Written Requests. The issuance of a Written Request does not require the sponsor to undertake the described studies.

U.S. regulation of companion diagnostics

Our product candidates may require use of an *in vitro* diagnostic to identify appropriate patient populations. These diagnostics, often referred to as companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import and post-market surveillance. Unless an exemption applies, companion diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval.

If use of companion diagnostic is essential to safe and effective use of a drug or biologic product, then the FDA generally will require approval or clearance of the diagnostic contemporaneously with the approval of the therapeutic product. On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for "*In Vitro* Companion Diagnostic Devices." According to the guidance, for novel candidates such as our product candidates, a companion diagnostic device and its corresponding drug or biologic candidate should be approved or cleared contemporaneously by FDA for the use indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a biologic product candidate generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption, or

IDE, regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE. In July 2016, the FDA issued a draft guidance document intended to further assist sponsors of therapeutic products and sponsors of *in vitro* companion diagnostic devices on issues related to co-development of these products.

The FDA generally requires companion diagnostics intended to select the patients who will respond to cancer treatment to obtain approval of a PMA for that diagnostic contemporaneously with approval of the therapeutic. The review of these *in vitro* companion diagnostics in conjunction with the review of therapeutic candidates involves coordination of review by the FDA's Center for Biologics Evaluation and Research and by the FDA's Center for Devices and Radiological Health. The PMA process, including the gathering of clinical and preclinical data and 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 reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are also subject to an application fee.

PMAs for certain devices 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 produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. In addition, as part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or a not-approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA, such as changes in labeling, or 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.

If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will issue an order denying approval of the PMA or issue a not approvable order. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing. 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.

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 establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. 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.

European Union Drug Development

In the European Union, or EU, clinical and commercial drug products are subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU member states

have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the member state where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical.

European Union Drug Review and Approval

In the European Economic Area, or EEA, which is comprised of the 27 member states of the EU and Iceland, Liechtenstein, Norway, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the member states of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a member state of the EEA, this National MA can be recognized in other member states through the Mutual Recognition Procedure. If the product has not received a National MA in any member state at the time of application, it can be approved simultaneously in various member state through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the member state in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other member state, referred to as the Member States Concerned, for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the member states (i.e., in the RMS and the Member States Concerned). Under the above described procedures, before granting the MA, the EMA or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

European Union Orphan Designation and Exclusivity

In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union community (or where it is unlikely that the development of the medicine would generate sufficient return to justify the investment) and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or, if a method exists, the product would be a significant benefit to those affected).

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation must be requested before submitting an application for MA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

European Union Drug Marketing

Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European countries, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization as well as the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Data Protection

In the ordinary course of our business, we process personal data (including sensitive health-related data). Accordingly, we are, and may in the future become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. Such obligations may include, without limitation, the European Union's General Data Protection Regulation 2016/679 ("EU GDPR") and the EU GDPR as it forms part of United Kingdom ("UK") law by virtue of section 3 of the European Union (Withdrawal) Act 2018 ("UK GDPR"). Several states within the United States have enacted or proposed data privacy laws. Additionally, we are, or may become, subject to various U.S. federal and state consumer protection laws which require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

Numerous U.S. states have enacted comprehensive consumer privacy laws that impose certain obligations on covered businesses, including the provision of specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business. Certain states also impose stricter requirements for processing certain personal data, including sensitive health data, such as conducting data privacy impact assessments. These state laws often allow for the imposition of statutory fines for noncompliance. Outside the United States, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. See the section titled "We and the third parties with whom we work are subject to rapidly changing and increasingly stringent U.S. and foreign laws, regulations, and rules; contractual obligations; industry standards; policies and other obligations relating to privacy, data protection and information security. Our actual or perceived failure (or that of the third parties with whom we work) to comply with these obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of business operations; reputational harm; loss of revenue or profits; and other adverse business consequences." for additional information about the laws and regulations to which we may become subject and about the risks to our business associated with such laws and regulations.

Rest of the World Regulation

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Coverage and Reimbursement

Sales of our products, when and if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States, no uniform policy of coverage and reimbursement for drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. As a result,

coverage determination is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Additionally, we, or our collaborators, will be required to obtain coverage and reimbursement for our companion diagnostic tests separate and apart from the coverage and reimbursement we may seek for our product candidates.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of biosimilars for branded prescription drugs. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years and biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide coverage and reimbursement. Obtaining coverage and adequate reimbursement for newly approved drugs and biologics is a time-consuming and costly process, and coverage may be more limited than the purposes for which a drug is approved by the FDA or comparable foreign regulatory authorities. Assuming coverage is obtained for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Additionally, coverage policies and third-party reimbursement rates may change at any time. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of prescribed products.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. 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 of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Employees and Human Capital Resources

In November 2025, as part of cash preservation measures associated with our previously announced strategic review process, our Board of Directors approved a reduction in force of approximately 65% of our workforce, or the 2025 Restructuring. The 2025 Restructuring was substantially completed during the fourth quarter of 2025. We incurred total charges of approximately $1.7 million in connection with the 2025 Restructuring, consisting primarily of one-time employee termination costs, including severance payments and other employee termination-related expenses, that were contingent upon the impacted employees' execution and non-revocation of separation agreements. Substantially all of the 2025 Restructuring costs were recorded in 2025, with none expected to be recorded in 2026.

As of March 23, 2026, we had 29 full-time employees, including 23 employees who joined in connection with our acquisition of Faeth. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. In connection with the Acquisition, our near-term human capital priorities include the successful integration of former Faeth personnel and the continued development of our organization to support the advancement of our clinical programs, including our planned breast cancer trial. We anticipate selectively expanding our workforce as our clinical and operational needs evolve. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of stock-based compensation awards in order to increase stockholder value and the success of our Company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate Information

Our common stock is listed on The Nasdaq Capital Market under the symbol “SNSE”.

We were originally incorporated as Panacea Pharmaceuticals, Inc., or Panacea, under the laws of the state of Maryland in 1999. In December 2017, we reincorporated in Delaware and changed our name to Sensei Biotherapeutics, Inc. Our principal executive offices are located at 1405 Research Blvd, Rockville, MD 20850. Our telephone number is (240) 243-8000.

The Faeth design logo, “Faeth”, “Faeth Therapeutics,” and our other registered or common law trademarks, service marks, or trade names appearing in this Report are the property of Sensei Biotherapeutics, Inc. Other trade names, trademarks and service marks used in this Report are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this Report exclude the ® or TM symbols.

Available Information

Our website address is www.senseibio.com. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Exchange Act are made available free of charge on or through our website as soon as reasonably practicable after such reports are filed with, or furnished to, the United States Securities and Exchange Commission, or SEC. The information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC, and any references to our website are intended to be inactive textual references only.

Item 1A. Risk Factors.

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

SUMMARY OF RISK FACTORS

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

- We have a limited operating history, have incurred net losses since our inception, and anticipate that we will incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, may not be able to sustain it.
- If we are unable to raise additional capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.
- We need substantial additional funding to complete the development of our product candidates. A failure to obtain this necessary capital when needed could force us to further delay, limit, reduce or terminate our product development or commercialization efforts.
- We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.
- Our development efforts are in the early stages. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Our business is highly dependent on the success of our product candidates that we advance into the clinic. All our product candidates will require significant additional preclinical, clinical and manufacturing development before we may be able to seek regulatory approval for and launch a product commercially. If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Interim data from our clinical trials that we announce or publish from time to time may change as more patients are enrolled and additional data become available.
- We will depend on timely enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Clinical trials are difficult to design and implement, can be lengthy and expensive, involve uncertain outcomes and may not ultimately be successful.
- We were not involved in the early development of PIKTOR; therefore, we are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical and clinical trials of PIKTOR.
- While emerging clinical data from a competitor has provided evidence supporting the multi-node inhibition concept, there is no guarantee that PIKTOR's specific approach will produce comparable results, and a competitor's first-mover advantage could limit our commercial opportunity.

- We rely, and expect to continue to rely, on third parties to conduct the preclinical and clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements.
- If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if approved.
- We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- The success of our product candidates will depend on several factors, including obtaining and maintaining patent and trade secret protection and/or regulatory exclusivity for our product candidates.
- If we are unable to obtain and maintain patent protection for our technologies and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.
- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.
- There is no guarantee that the Acquisition will increase stockholder value.
- Pursuant to the terms of the Acquisition and related 2026 Private Placement, we are required to recommend that our stockholders approve the conversion of all outstanding shares of our Series B Preferred Stock into shares of our common stock. We must also obtain stockholder approval of an amendment to our certificate of incorporation to increase the number of shares we are authorized to issue. We cannot guarantee that our stockholders will approve these matters, and if they fail to do so we may be required to settle such shares in cash and our operations would be materially harmed.
- The failure to successfully integrate the businesses of Sensei and Faeth in the expected timeframe could adversely affect our results of operations, financial condition, and future results.

Risks Related to Our Financial Position

We have a limited operating history and have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.

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

We have incurred significant net losses since our inception. Our net loss was $21.1 million and $30.2 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $283.1 million. We have funded our operations to date primarily with proceeds from the sale of our equity securities and borrowings of convertible debt.

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

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

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

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

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

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

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

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

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

- complete our ongoing and planned clinical trials, preclinical studies and IND-enabling activities;
- initiate, enroll, and complete additional clinical trials for our product candidates;
- seek and obtain regulatory approvals for our product candidates;
- build and maintain our manufacturing capabilities or enter into third-party manufacturing arrangements;
- expand and protect our intellectual property portfolio; and
- fund our general and administrative operations.

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

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

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

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

To the extent that we raise additional capital through the sale of equity, warrants to purchase equity, and/or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity financing, if available, could result in fixed payment obligations, and we may be required to accept terms that restrict our ability to incur additional indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions.

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

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

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

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

impacting international trade agreements or imposing trade restrictions such as tariffs and retaliatory counter measures.

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

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

Risks Related to the Development of our Product Candidates

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

There is no assurance that any clinical trials of our product candidates will be successful or will generate positive clinical data and we may not receive marketing approval from the FDA or other regulatory agencies for any of our product candidates. All our product candidates are in the early stages of our development efforts, and if any of our product candidates encounter safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and forecasted timelines and business could be significantly harmed. While the FDA has not objected to our protocol for PIKTOR in HR+/HER2- breast cancer and we intend to initiate a Phase 1b clinical trial in the first half of 2026, there can be no assurance that the FDA will permit any future IND or protocol for our other product candidates or additional indications to go into effect in a timely manner or at all. We would not be permitted to conduct further clinical trials in the United States without future INDs and approved protocols for our other product candidates.

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

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

- maintaining and growing an organization of scientists, medical professionals and business people who can develop and commercialize our product candidates and technology.

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

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

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

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

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

- disagreement with the design, protocol or conduct of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of an NDA or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or our facilities;
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval; or
- lack of adequate funding to complete a clinical trial in a manner that is satisfactory to the applicable regulatory authority.

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

The FDA or a comparable regulatory authority may require more information, including additional preclinical or clinical data to support approval, including data that would require us to perform additional clinical trials or modify our manufacturing processes, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we change our manufacturing processes, we may

be required to conduct additional clinical trials or other studies, which also could delay or prevent approval of our product candidates. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer indications than we request (including failing to approve the most commercially promising indications), may limit indications, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing commitments, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

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

Our business is highly dependent on the success of our product candidates that we advance into the clinic, particularly PIKTOR. All of our product candidates, including PIKTOR, will require significant additional preclinical, clinical and manufacturing development before we may be able to seek regulatory approval for and launch a product commercially and we may not be successful in our efforts.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We are devoting substantially all our resources to the development of PIKTOR. Our existing clinical data for PIKTOR is derived from a Phase 1b open-label, uncontrolled study with a limited number of evaluable patients. If PIKTOR encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and forecasted timelines and business could be significantly harmed. Because substantially all of our resources are concentrated on a single product candidate, any failure or significant delay in PIKTOR's development would have a disproportionate impact on our business, financial condition and prospects, and we do not have other clinical-stage programs that could offset such a setback.

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

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

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

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

While emerging clinical data from third parties has provided evidence supporting the multi-node inhibition concept for the PI3K/AKT/mTOR pathway, there is no guarantee that PIKTOR's specific approach will produce comparable clinical results, and earlier approvals for third party drugs in this class could limit our commercial opportunity.

Our development strategy for PIKTOR is premised on the hypothesis that simultaneous inhibition of multiple nodes of the PI3K/AKT/mTOR signaling pathway — specifically, concurrent PI3Kα inhibition and mTORC1/2 inhibition — will provide deeper, more durable and more tolerable pathway suppression than currently approved single-node inhibitors. We refer to this approach as multi-node inhibition, or MNI. While recent Phase 3 data for the IV pan-PI3K and mTORC1/2 inhibitor gedatolisib provide clinical evidence supporting the broader MNI concept, there can be no assurance that PIKTOR will produce comparable efficacy or tolerability results in clinical trials.

If gedatolisib receives regulatory approval, it would become the first approved MNI therapy for HR+/HER2- advanced breast cancer and could establish a significant market position before PIKTOR completes clinical development. In that event, PIKTOR would need to demonstrate meaningful differentiation — whether through oral convenience, a favorable tolerability profile, broader patient applicability, or other clinical advantages — in order to compete effectively. There can be no assurance that PIKTOR will be able to demonstrate such differentiation. Furthermore, the PI3K/AKT/mTOR pathway is the subject of intense research, and new modalities or approaches could emerge that are superior to both gedatolisib and PIKTOR, rendering our competitive position obsolete.

In addition, if gedatolisib or another MNI receives regulatory approval and is incorporated into the standard of care for any of our target indications, regulatory authorities may require that future clinical trials of PIKTOR, including any registrational trials, use the newly approved MNI as part of the comparator arm rather than the current standard of care. Such a change could require us to conduct larger, more expensive, and longer clinical trials than currently planned, raise the efficacy threshold that PIKTOR must demonstrate to achieve regulatory approval, and materially increase our development costs and delay our anticipated development timelines. Even if we are able to demonstrate superiority or non-inferiority to a newly approved MNI, the cost, complexity, and duration of the required trials could substantially exceed our current projections, and we may need to raise additional capital to fund such trials. There can be no assurance that we would be able to obtain such additional capital on acceptable terms, or at all.

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

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

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

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

- the FDA or other comparable regulatory authority may disagree as to the number, design or implementation of our clinical trials, or may not interpret the results from clinical trials as we do;

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results;
- we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or abandon our product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit suitable patients to participate in a trial;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA or other comparable regulatory authorities may fail to approve our manufacturing processes or facilities;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the clinical trials; and
- the approval policies or regulations of the FDA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

In addition, our ongoing Phase 2 trial in advanced endometrial cancer, Study FTH-PIK-201, includes an optional sub-study in which enrolled patients may combine an insulin-suppressing diet with their PIKTOR plus paclitaxel treatment regimen. Because participation in the diet sub-study is optional, patients who elect to participate may differ in meaningful ways from those who do not, and the resulting patient subgroups may not be balanced with respect to baseline characteristics or other factors that could influence clinical outcomes. If a significant proportion of patients participate in the diet sub-study, or if the diet has any effect — whether positive or negative — on efficacy or tolerability endpoints, it may be difficult to attribute observed clinical outcomes solely to PIKTOR. This could complicate our ability to interpret the trial's results, could raise questions from regulatory authorities, and could reduce the evidentiary value of the trial for purposes of supporting future regulatory submissions or clinical development decisions.

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

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

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

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

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. For example, we are currently focusing the majority of our efforts on the development of PIKTOR. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

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

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

We were not involved in the early development of PIKTOR; therefore, we are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical and clinical trials of PIKTOR.

We had no involvement with or control over the initial preclinical and clinical development of PIKTOR. We are dependent on third parties having conducted their research and development in accordance with the applicable protocols and legal, regulatory and scientific standards; having accurately reported the results of all preclinical studies and clinical trials conducted with respect to such drug product; and having correctly collected and interpreted the data from these trials. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of PIKTOR will be delayed and may be adversely affected.

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

We expect to publish from time to time interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

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

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

The cross-trial comparisons we present regarding PIKTOR's safety and efficacy profile relative to other PI3K/AKT/mTOR pathway agents are subject to significant limitations and may not be predictive of PIKTOR's relative performance in future controlled studies.

In this Report and in our other public communications, we present data comparing PIKTOR's emerging clinical profile, including rates of hyperglycemia and stomatitis, pharmacokinetic and pharmacodynamic characteristics, and preclinical potency, to published data from clinical trials of approved single-node inhibitors and other multi-node inhibitors in development. These comparisons are derived from different clinical trials conducted at different times, with differences in trial design, patient populations, disease settings, dosing regimens, endpoints, sample sizes, follow-up periods, and adverse event grading criteria. No head-to-head clinical trials have been conducted comparing PIKTOR to any of the agents referenced in these comparisons, and cross-trial comparisons are inherently limited and may not accurately reflect the relative safety or efficacy of the agents being compared.

Physicians, patients, investors, and regulatory authorities may draw conclusions from these cross-trial comparisons that are not supported by the underlying data, or may discount PIKTOR's potential based on the inherent limitations of such comparisons. If PIKTOR's clinical profile does not compare as favorably to competing agents in head-to-head or registrational trials as our cross-trial analyses suggest, the commercial prospects and perceived differentiation of PIKTOR could be materially diminished.

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

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

- the patient eligibility criteria defined in the protocol;
- the number of patients with the disease or condition being studied;
- the perceived risks and benefits of the product candidate in the trial, including with respect to PIKTOR, perceived risks related to results of prior trials of serabelisib and sapanisertib alone or in combination;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- clinicians' and patients' perceptions as to any risks associated with our competitors' product candidates;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion of their treatment; and
- factors we may not be able to control, such as pandemics, that may limit patients, principal investigators or staff or clinical site available.

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

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

The market opportunities for certain of our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and, therefore, may be small, and our projections regarding the size of the addressable market may be incorrect.

Our approach is based on multi-node inhibition of the PI3K/AKT/mTOR pathway. While emerging Phase 3 data from a competitor have provided clinical evidence supporting this broader concept, our specific product candidate, PIKTOR, has not been evaluated in registrational clinical trials, which makes it difficult for us to predict the time and cost of product development and potential for regulatory approval. Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When cancers are detected they are treated with first line of therapy with the intention of curing the cancer.

This treatment generally consists of chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. If the patient's cancer relapses, then the patient is given a second line or third line therapy, which can consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. Generally, the higher the line of therapy, the lower the chance of a cure. With third or higher line, the goal of the therapy is to control the growth of the tumor and extend the life of the patient, as a cure is unlikely to happen. Patients are generally referred to clinical trials in these situations.

There is no guarantee that any of our product candidates, even if approved, would be approved for an early line of therapy. In addition, we may have to conduct additional large randomized clinical trials prior to gaining approval for the earlier line of therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the size of the patient population subset of people with these cancers in a position to receive first, second, third and fourth line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be fewer than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve significant revenues without obtaining regulatory approval for additional indications or as part of earlier lines of therapy.

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

We have made internal estimates of the total addressable market for PIKTOR and other product candidates targeting the PI3K/AKT/mTOR pathway, including estimates of patient populations, treatment penetration rates, and potential pricing. These estimates are based on a variety of sources, including published scientific literature, epidemiological data, market research and our own assumptions about competitive dynamics. However, these estimates are inherently uncertain and may prove to be materially incorrect.

The actual addressable market for PIKTOR may be smaller than we estimate for several reasons, including: the number of patients with actionable alterations in the PI3K/AKT/mTOR pathway may be lower than projected; physicians may not adopt PIKTOR over established therapies; payors may restrict reimbursement; PIKTOR may initially be approved only for later-line treatment settings with smaller patient populations; competing products may capture significant market share before PIKTOR reaches the market; and advances in precision oncology may further segment the patient population. If the actual market opportunity for PIKTOR is materially smaller than our estimates, we may not be able to generate sufficient revenue to justify our development investment, which could have a material adverse effect on our business and financial condition.

In particular, our estimates of PIKTOR's addressable market include an assumption that multi-node inhibition may confer clinical benefit to patients whose tumors are activated through the PI3K/AKT/mTOR pathway in its non-mutated, or "wild-type," state, either through dysregulated upstream signaling or as an adaptive response to prior therapy. This belief is based on limited clinical data from a small number of patients in an open-label, uncontrolled Phase 1b study in which responses were observed across multiple mutational classifications, including in patients with no detectable pathway mutations, and on our interpretation of PIKTOR's mechanism of action. These observations have not been confirmed in larger or controlled clinical trials and may not be replicated in our ongoing or planned studies. If multi-node inhibition does not demonstrate meaningful clinical benefit in patients without direct PI3K/AKT/mTOR pathway alterations, the addressable patient population for PIKTOR could be significantly smaller than we currently estimate, which would reduce our anticipated commercial opportunity and could have a material adverse effect on our business, financial condition, and prospects.

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

Our clinical trials will include cancer patients who are very sick and whose health is deteriorating. It is possible that some of these patients may experience side effects during our clinical trials. For example, in a prior clinical trial of PIKTOR, it was reported that one patient had Grade 3 septic shock that was determined to be drug-

related. In addition, PI3K and mTOR inhibitors as a class are associated with known adverse effects including hyperglycemia, stomatitis, diarrhea, rash and hepatotoxicity. These class-effect toxicities have been observed with approved drugs targeting this pathway and may also be associated with PIKTOR. If these or other adverse effects occur with unacceptable frequency or severity in our clinical trials, our ability to develop and commercialize PIKTOR could be materially impaired. Further, patients may die during our clinical trials for various reasons. The causes of death could include receiving our product candidates because the patient's disease is too advanced or because the patient experiences medical problems that may not be related to our product candidate. Even if the patient deaths are not related to our product candidate, the deaths could affect perceptions regarding the safety of our product candidates. Patient deaths and severe side effects caused by our product candidates, or by products or product candidates of other companies that are thought to have similarities with our product candidates, could result in the delay, suspension, clinical hold or termination of our clinical trials, the FDA or other regulatory authorities for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates would be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

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

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

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

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

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

may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

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

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

Risks Related to Manufacturing and our Dependence on Third Parties

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

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

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

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

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

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

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

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

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

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

Certain of our current and future product candidates will be evaluated in combination with third-party drugs, and we will have limited or no control over the supply, regulatory status, or regulatory approval of such drugs.

Our ability to develop and ultimately commercialize current and future product candidates used in combination with other compounds will depend on our ability to access such drugs on commercially reasonable terms for clinical trials and their availability for use with the commercialized product, if approved. Any failure to enter into successful commercial relationships, or inability to source or purchase other potential combination agents in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop current and future product candidates as potential combination therapies, which may materially harm our business, financial condition, results of operations, stock price and prospects. Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not encountered when developing single-agent product candidates. For example, the FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. Additionally, following product approval, the FDA may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party under terms unfavorable to us to satisfy such a requirement. Moreover, developments related

to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, and changes to the standard of care.

We currently rely on CMOs for the production of PIKTOR and we expect to rely on CMOs for our other product candidates. This reliance on CMOs increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

Because PIKTOR is a combination of two active pharmaceutical ingredients, our manufacturing and supply chain for PIKTOR requires coordination across two separate drug substances, and any disruption to the supply of either component could halt our entire development program. The need to maintain parallel supply chains for two drug substances increases our operational complexity and our vulnerability to supply disruptions compared to single-agent product candidates. We may not be able to secure backup suppliers for both components on commercially reasonable terms. Any significant delay in the supply of either serabelisib or sapanisertib could considerably delay our clinical development, increase our costs, and have a material adverse effect on our business.

We currently have no plans to build our own clinical or commercial scale manufacturing capabilities for our product candidates. Instead, we expect to rely on third parties for the manufacture of our product candidates and related raw materials for future preclinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. We have entered into arrangements with a limited number of third-party contract manufacturing organizations, or CMOs, as part of our development of our product candidates. These CMOs will provide drug substance intermediate and drug product that will be subsequently labeled, packaged and distributed to our CROs. We may also enter into agreements with additional companies for the supply of substances for use in the development of our product candidates or any future product candidates or for the manufacture of such product candidates.

We or our third-party suppliers or manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredient, or API, necessary to produce product candidates we may develop in the quantities needed for our clinical trials or, if any current or future product candidates we may develop are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or API, including shortages caused by the purchase of such raw materials or API by our competitors or others. Even if raw materials or API are available, we may be unable to obtain sufficient quantities at an acceptable cost or quality. The need to synchronize the procurement of two APIs for our fixed combination drug product candidate PIKTOR presents additional risk since any imbalance in availability and timing of one API would prevent the manufacture of finished drug product for clinical trials or commercial use. The failure by us or our third-party suppliers or manufacturers to obtain the raw materials or API necessary to manufacture sufficient quantities of any current or future product candidates we may develop could delay, prevent or impair our development efforts and may have a material adverse effect on our business.

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

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we do not intend to begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of any of our product candidates. Additionally, any changes implemented by a new

CMO could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our current and future product candidates and jeopardize our ability to commence product sales and generate revenue.

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

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

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

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

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

Any product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time-

consuming to implement. We do not currently have arrangements in place for redundant supply or second sources of supply with alternative suppliers or CMOs to supplement or supply the raw materials, drug substances, intermediates, and drug product necessary for the manufacture of our product candidates, including PIKTOR. If our current third-party CMO cannot perform as agreed, we may be required to replace such manufacturer and we may be unable to replace them on a timely basis or at all.

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

We rely on third-parties to supply certain raw materials necessary to produce our drug candidates for preclinical studies and clinical trials. For example, we rely on third-parties to supply certain reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources. There are a small number of suppliers for certain raw materials that we use to manufacture our drug candidates. Certain of our suppliers or their sub-suppliers are based in China, which exposes us to additional risks including trade restrictions, tariffs, export controls, geopolitical tensions, and potential disruptions to the supply chain that are beyond our control. We work with our CMOs to purchase these materials from our suppliers who may not always have long-term supply agreements in place, which could expose us to a variety of risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to our contract manufacturing caused by problems at suppliers could delay shipment of our product candidates, increase our cost of goods sold and result in lost sales with respect to any approved products. Any significant delay in the supply of raw materials for our drug candidates for a preclinical study or a clinical trial due to the need to replace a third-party supplier could considerably delay completion of certain preclinical studies and/or clinical trials. Moreover, if we are unable to purchase sufficient raw materials after regulatory approval for our drug candidates, the commercial launch of our drug candidates could be delayed, or there could be a supply shortage, each of which could impair our ability to generate revenues from their sale.

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

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

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

contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

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

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

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

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

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

In connection with the clinical development of our product candidates for certain indications, we may develop or engage third parties to develop or obtain access to in vitro companion diagnostic tests to identify patient subsets within a disease category who may derive benefit from our product candidates. Such companion diagnostics may be used during our clinical trials and may be required in connection with the FDA approval of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. Companion diagnostics are subject to regulation by the FDA, EMA and other regulatory authorities as medical devices and require separate regulatory approval prior to commercialization.

We may rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. We and our future collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics. We and our future collaborators also may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial

scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval or such approval may be delayed, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue developing, selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our therapeutic product candidates.

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal civil and criminal false claims, including the federal FCA, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;

- HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal physician payment transparency requirements, sometimes referred to as the “Sunshine Act” under the ACA, require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report to the Centers for Medicare & Medicaid Services, or CMS, information related to transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other

healthcare professionals (such as nurse practitioners and physicians assistants), and teaching hospitals, as well as information regarding ownership and investment interests of such physicians and their immediate family members;

- HIPAA, as amended by HITECH and its implementing regulations, impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Some state and local laws require certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales representatives. Further, many state laws governing the privacy and security of health information in certain circumstances, differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

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

There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on July 4, 2025, the OBBBA was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The

OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

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

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

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

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

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

- the availability of capital.

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

We are subject to the U.K. Bribery Act 2010, or the Bribery Act, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

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

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

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

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations 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. We also could incur significant costs associated with civil or criminal fines and penalties. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our

research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

Risks Related to the Commercialization of our Product Candidates

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

We currently plan to work to build our commercialization capabilities internally over time such that we are able to commercialize any product candidate for which we may obtain regulatory approval. However, we currently have no sales, marketing or distribution capabilities and have no experience in marketing or distributing pharmaceutical products. To achieve commercial success for any product candidate for which we may obtain marketing approval, we will need to expand our sales and marketing organization and establish logistics and distribution processes to commercialize and deliver our product candidates to patients and healthcare providers. These activities will be expensive and time-consuming and will require significant attention of our executive officers to manage. There are risks involved in establishing our own sales and marketing capabilities, as well as with entering into arrangements with third parties to perform these services. Additionally, our beliefs that our products will be commercially viable have not been tested.

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

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

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

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

We anticipate that we will compete with Alpelisib, Inavolisib, Capivasertib, Everolimus and Temsirolimus, all of which are approved drugs that target the PI3K/AKT/mTOR pathway. In addition, we are aware of several additional product candidates in clinical development that could potentially pose a direct competitive threat to PIKTOR, particularly for the treatment of advanced HR+/HER2- breast cancer. These product candidates include Gedatolisib, an IV pan-PI3K + mTORC1/2 inhibitor from Celcuity, whose New Drug Application for HR+/HER2-, PIK3CA wild-type metastatic breast cancer was accepted by the FDA with Priority Review and a Prescription Drug

User Fee Act goal date of July 17, 2026; Tersolisib, an oral mutant-specific PI3Kα inhibitor from Eli Lilly currently in Phase 3 trials for HR+/HER2- breast cancer; Zovegalisib, an oral mutant-selective PI3Kα inhibitor from Relay Therapeutics currently in Phase 3 trials for advanced HR+/HER2- breast cancer; Afuresertib, an oral pan AKT inhibitor from Laekna Therapeutics currently in Phase 3 trials for advanced HR+/HER2- breast cancer; Paxalisib, an oral brain penetrant PI3K/mTOR inhibitor from Kazia Therapeutics currently in Phase 3 trials in glioblastoma; SNV4818, an oral pan-mutant-selective PI3Kα inhibitor acquired by Novartis from Synnovation Therapeutics in March 2026, currently in Phase 1/2 trials for HR+/HER2- breast cancer and other solid tumors; and OKI-219, an oral mutant-specific PI3Kα inhibitor from OnKure Therapeutics, currently in Phase 1/2 trials for HR+/HER2- breast cancer and other solid tumors. Our competitive thesis is that multi-node inhibition is a superior mechanism to provide deeper, more tolerable suppression of the PI3K/AKT/mTOR pathway than is currently available in approved therapeutics. If our thesis is incorrect, or if new modalities are developed that better suppress the PI3K/AKT/mTOR pathway, our business would be materially and adversely impacted.

Several of these competing product candidates are in Phase 3 registrational trials with potential approval timelines that are ahead of our development timeline for PIKTOR. In particular, Celcuity recently had its New Drug Application for gedatolisib in HR+/HER2-, PIK3CA wild-type metastatic breast cancer accepted by the FDA with Priority Review and a Prescription Drug User Fee Act goal date of July 17, 2026. If one or more competitors obtains regulatory approval and establishes a market position before we are able to enter the market, it could significantly diminish the commercial opportunity for PIKTOR, particularly if the approved product addresses the same patient population or demonstrates a superior safety or efficacy profile. Additionally, mutant-selective PI3Ka inhibitors being developed by Eli Lilly (tersolisib) and Relay Therapeutics (zovegalisib) are also in Phase 3 development and, if approved, could reduce the addressable market for PIKTOR by providing an alternative targeted approach for patients with PI3K-mutant tumors. Large pharmaceutical companies are making significant investments in the PI3K/AKT/mTOR space. For example, in March 2026, Novartis announced the acquisition of Synnovation Therapeutics' pan-mutant-selective PI3Kα inhibitor program, including SNV4818, which is currently in Phase 1/2 clinical development for HR+/HER2- breast cancer. This and similar acquisitions could result in additional well-resourced competitors with established commercial infrastructure entering the market ahead of or concurrent with PIKTOR, which could significantly diminish our commercial opportunity.

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

Many of our competitors, either alone or with their strategic collaborators, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than we are in obtaining approval for treatments and achieving widespread market acceptance, which may render our treatments obsolete or non-competitive. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

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

Even if any of our product candidates 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.

Even if we obtain approvals from the FDA or other comparable regulatory agencies and are able to initiate commercialization of our product candidates or any other product candidates we develop, the product candidate may

not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers, and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage, adequate reimbursement from, and our ability to negotiate pricing with, third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts and distribution support.

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

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

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

Market acceptance and sales of any product candidates, if approved, that we commercialize will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, one payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment will be approved. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may incur significant costs to conduct expensive pharmaco-

economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor's formulary generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, and providers are unlikely to prescribe our products, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products and their administration. Therefore, coverage and adequate reimbursement is critical to new medical product acceptance.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which could negatively impact prescriptions for our product candidates, if approved.

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

In addition, our NEAAR program, which seeks to restrict patient intake of specific non-essential amino acids to suppress tumor growth, represents a novel therapeutic approach for which there is limited regulatory precedent. Dietary interventions are not subject to the same well-established regulatory approval pathways as pharmaceutical products, and it is unclear how the FDA or comparable foreign regulatory authorities would evaluate a dietary regimen as a component of a cancer treatment regimen. Even if we are able to generate clinical evidence supporting the use of NEAAR in combination with our other product candidates, third-party payors may be unwilling to provide coverage or reimbursement for a prescribed dietary intervention, which could limit patient adoption and reduce any potential commercial value of the program.

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. 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. There is no guarantee that any

patent application we file will result in an issued patent having claims that protect our products; and, as a result, we may not be able to effectively prevent others from commercializing competitive products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar patent protection covering our products in all jurisdictions where we file patent applications. If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any product candidate, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize any product candidates that are approved. Any such outcome could have a materially adverse effect on our business.

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

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

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

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our

claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. The scope of patent protection may also be limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

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

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products or pipeline candidates. We may incorrectly determine that our products are not covered by a third-party patent. Further, we may conclude that a well-informed court or other tribunal would find the claims of a relevant third-party patent to be invalid based on prior art, enablement, written description, or other ground, and that conclusion may be incorrect, which may negatively impact our ability to market our products or pipeline molecules.

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

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

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

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

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, all European patents, including those issued prior to June 1, 2023, now by default automatically fall under the jurisdiction of a new European Unified Patent Court, or the UPC, for litigation involving such patents. As the UPC is a relatively new court system, there is uncertainty regarding litigation at the UPC. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain a pan-European injunction. It is uncertain how the UPC will impact granted European patents in the pharmaceutical industry.

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

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

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

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

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

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

Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, product candidate(s), or the use of our product candidate(s). As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that may be infringed by the manufacture, use, or sale of our technologies or product candidate(s) or will prevent, limit, or otherwise interfere with our ability to make, use, or sell our technologies and product candidate(s).

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

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

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

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract

our management and other employees. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

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

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

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

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

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

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

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the

technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, written description, or lack of patentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant material information from the USPTO or made a materially misleading statement during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. Because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly and decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention or that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.

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

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

Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the market price of common shares. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

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

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

In addition, while we require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us asserting ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

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

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

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

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and our collaborators;
- the priority of invention of patented technology.

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

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

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

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

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

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

In addition, any proprietary name we propose to use with our product candidates or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors, and others located

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

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business,

could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not being approved, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Governments of some foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. In addition, many countries limit the enforceability of patents against government agencies or government contractors. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies and product candidate(s). While we will endeavor to try to protect our technologies and product candidate(s) with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive, and unpredictable.

In addition, geopolitical actions in the United States and in other countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any future licensors and the maintenance, enforcement, or defense of our issued patents or those of any future licensors. As a result, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

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

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

Risks Related to our Business Operations

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

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

divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

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

The Acquisition resulted in a combined management team that is small relative to our development ambitions. We are heavily dependent on a limited number of individuals with specialized expertise in PI3K/AKT/mTOR pathway biology, metabolic oncology, and clinical development of combination products. The loss of one or more of these individuals, particularly during the critical post-Acquisition integration period, could significantly delay our clinical development programs. Competition for individuals with this specialized expertise is intense, and we may not be able to recruit suitable replacements on acceptable terms or in a timely manner.

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

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

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

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

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

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses, as we may deem

appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including:

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

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

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

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

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

We do not currently maintain product liability insurance because we have determined that the cost of available coverage is not justified relative to our current stage of clinical development. Once we are ready for a product launch, we intend to bind a policy with product liability insurance coverage in the aggregate and a per incident limit at an amount adequate to cover estimated liabilities that we may incur. We may need to increase our insurance coverage if we re-initiate our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

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

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

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

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

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

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

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

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

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

A significant portion of our total outstanding shares may be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our shares of common stock in the public market, the market price of our common stock could decline significantly.

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

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

Finally, in connection with the execution of the Agreement and Plan of Merger, or the Merger Agreement, dated as of February 17, 2026, by and among the Company, Sapphire First Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of the Company, Sapphire Second Merger Sub, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company, Faeth Subsidiary and Faeth HoldCo, certain of our directors and officers, as well as certain of the directors, officers and stockholders of Faeth Therapeutics, each as of immediately prior to the Acquisition, entered into lock-up agreements, pursuant to which each such stockholder will be subject to a 180-day lockup on the sale or transfer of shares of our common stock and Series B Preferred Stock held by each such stockholder, including those shares received by directors and officers in the Acquisition, subject to certain limited exceptions as set forth in such lock-up agreements. Upon expiration of this 180-day lockup period, these shares will become eligible for sale in the public market. Pursuant to the Merger Agreement and the registration rights agreement that we entered into pursuant to the 2026 Private Placement, we are obligated to prepare and file a resale registration statement with the SEC to register the resale of shares of our common stock underlying the Series B Preferred Stock and warrant to purchase shares of Series B Preferred Stock. We will use commercially reasonable efforts to cause this registration statement to be declared effected by the SEC. Once the registration statement is declared effective, the shares subject to the registration statement will no longer constitute restricted securities and may be sold freely in the public markets, subject to (i) the approval of the Company Stockholder Matters (as defined below), (ii) the approval of the Nasdaq Listing Application (as defined below) and (iii) any beneficial ownership limitations set by the holder of Series B Preferred Stock. If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline.

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

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

We are an "emerging growth company" and a "smaller reporting company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our shares of common stock less attractive to investors.

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including the auditor attestation requirements in the assessment of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, compliance with any new requirements adopted by the PCAOB, disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and the requirements of holding advisory "say-on-pay" votes on executive compensation and stockholder advisory votes on golden parachute compensation not previously approved. Certain of these reduced reporting requirements and exemptions are also available to us due to the fact that we qualify as a "smaller reporting company" under SEC rules. For instance, smaller reporting companies are not required to obtain an auditor attestation and report regarding management's assessment of internal control over financial reporting, are not required to provide a compensation discussion and analysis, are not required to provide a pay-for-performance graph or CEO pay ratio disclosure and may present only two years of audited financial statements and related MD&A disclosure.

Under the JOBS Act, we will remain an emerging growth company until the earliest of (1) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (3) the issuance, in any three-year period, by our company of more than $1.0 billion in non-convertible debt securities; and (4) December 31, 2026, which is the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act. Under current SEC rules, however, we will continue to qualify as a "smaller reporting company" for so long as (i) we have a public float (i.e., the market value of common equity held by non-affiliates) of less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700 million.

We cannot predict if investors will find our shares of common stock to be less attractive because we may rely on these exemptions. If some investors find our shares of common stock less attractive as a result, there may be a less active trading market for our shares of common stock, and our share price may be more volatile.

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

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

We do not intend to pay any cash dividends on our common stock in the foreseeable future and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. Therefore, you should not rely on an investment in our common stock to provide dividend income. Our board of directors has complete discretion as to whether to distribute dividends. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future

results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. As a result, capital appreciation, if any, on our common stock will be your sole source of gains for the foreseeable future.

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

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

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. U.S. federal NOLs generated in taxable years beginning before January 1, 2018 are permitted to be carried forward for only 20 taxable years under applicable U.S. federal income tax law. Under the Tax Cuts and Jobs Act of 2017, or the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, NOLs arising in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs generally will be limited in taxable years beginning after December 31, 2020 to 80% of current year taxable income. As of December 31, 2025, we had NOL carryforwards for federal and state income tax purposes of approximately $170.5 million and $98.9 million, respectively, a portion of which expired beginning in 2025. Net operating loss carryforwards generated after December 31, 2017 for federal tax reporting purposes of $137.2 million have an indefinite life. The remaining federal net operating losses are subject to a 20-year carryforward period.

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

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

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

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America, will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America, will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action for breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any claim or cause of action against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, or DGCL, our certificate of incorporation or our bylaws;
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws;
- any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any claim or cause of action against us or any of our current or former directors, officers or other employees that is governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants.

This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Securities Exchange Act of 1934, or the Exchange Act, or any claim for which the U.S. federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation will provide that the federal district

courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If any other court of competent jurisdiction were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Insiders have substantial influence over us and could cause us to take actions that may not be, or refrain from taking actions that may be, in our best interest or in the best interest of our stockholders.

We believe that our directors, executive officers and principal stockholders, together with their affiliates, own, in the aggregate, a substantial portion of our outstanding common stock. As a result, if these or certain of these stockholders were to choose to act together, they may be able to affect the outcome of matters submitted to our stockholders for approval, as well as our management and affairs, such as:

- the composition of our board of directors;
- the adoption of amendments to our certificate of incorporation and bylaws;
- the approval of mergers or sales of substantially all of our assets;
- our capital structure and financing; and
- the approval of contracts between us and these stockholders or their affiliates, which could involve conflicts of interest.

This concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company and making some transactions more difficult or impossible without the support of these stockholders, even if such transactions are beneficial to other stockholders;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- requiring us to engage in transactions that may not be agreeable to or in the best interest of us or other stockholders.

Risks Related to the Acquisition

Pursuant to the terms of the Acquisition, we are required to recommend that our stockholders approve the conversion of all outstanding shares of our Series B preferred stock into shares of our common stock. We must also obtain stockholder approval of an amendment to our certificate of incorporation to increase the number of shares we are authorized to issue. We cannot guarantee that our stockholders will approve these matters, and if they fail to do so we may be required to settle such shares in cash and our operations may be materially harmed.

Under the terms of the Merger Agreement and the 2026 Private Placement purchase agreement, as promptly as practicable following the date of the Merger Agreement and pursuant to the Nasdaq Stock Market Rules, we will call and hold a meeting of our stockholders to obtain the requisite approval from our legacy stockholders for, among other things, (i) the approval, in accordance with certain of the rules of Nasdaq of the conversion of the Series B Preferred Stock into shares of our common stock, or the Conversion Proposal, (ii) the approval of a "change of control" under Nasdaq Listing Rules 5110 and 5635(b), or the Change in Control Proposal, (iii) the amendment of our certificate of incorporation to authorize an increase of up to 300,000,000 shares of our common stock, or the Charter Amendment Proposal and, together with the Conversion Proposal and the Change in Control Proposal, the Company Stockholder Matters, (iv) the approval of (A) the 2026 Equity Incentive Plan, which will provide for new awards for a number of shares of our common stock not exceeding 10% of our fully diluted shares of capital stock outstanding immediately after the 2026 Private Placement, and subject to approval by our Board, and which will include an annual increase pursuant to an "evergreen" provision providing for an annual increase of up to 5% of the

total number of our fully diluted shares of capital stock outstanding as of the day prior to such increase and (B) the 2026 Employee Stock Purchase Plan, with a total pool of shares of our common stock not exceeding 1% of our fully diluted shares of capital stock outstanding immediately after the 2026 Private Placement, and which shall include an annual increase pursuant to an "evergreen" provision providing for an annual increase of up to 1% of the total number of our fully diluted shares of capital stock outstanding as of the day prior to such increase. If we fail to receive sufficient proxies to constitute a quorum or to obtain the required vote on the Company Stockholder Matters and/or our Nasdaq Listing Application is not approved, we would be required to adjourn the meeting one or more times for up to 30 days per adjournment. If stockholder approval of the Company Stockholder Matters or approval of the Nasdaq Listing Application are still not obtained following such adjournment(s), we will be obligated to continue soliciting stockholder approval at subsequent annual or special meetings of our stockholders, held at intervals of no more than six months, until such approvals are obtained, which would be time consuming and costly.

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

Additionally, if the Company Stockholder Matters are not approved by the date that is six months following the initial issuance date of the Series B Preferred Stock, the holders of the Series B Preferred Stock would be entitled to require us to settle their shares of our common stock underlying the Series B Preferred Stock for cash at a price per share equal to the fair value of our common stock at such time as described in the Certificate of Designation or Preferences, Rights and Limitations of the Series B Preferred Stock, or the Certificate of Designation. If we are forced to cash settle a significant amount of the shares of our common stock underlying the Series B Preferred Stock, it could materially affect our results of operations, business and financial condition.

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

Pursuant to the Merger Agreement, in order to permit the waiver of the beneficial ownership limitations applicable to the Series B Preferred Stock and take other actions following the consummation of the Acquisition, which would constitute a "change of control" under Nasdaq Listing Rule 5110(a), we are required to use our reasonable best efforts to file an initial listing application for our common stock on Nasdaq (the "Nasdaq Listing Application"). The Nasdaq Listing Application must be conditionally approved prior to the date of our stockholder meeting to approve the Company Stockholder Matters. If we fail to meet the Nasdaq listing requirements and Nasdaq does not approve the Nasdaq Listing Application, we will be required to adjourn our stockholder meeting to approve the Company Stockholder Matters one or more times for up to 30 days per adjournment, continue to use our reasonable best efforts to obtain approval of the Nasdaq Listing Application and to continue soliciting stockholder approval of the Company Stockholder Matters at subsequent annual or special meetings of our stockholders, held at intervals of no more than six months, until such approval and the approval of the Company Stockholder Matters are obtained, which would be time consuming and costly. Additionally, if the Company Stockholder Matters are not approved by the date that is six months following the initial issuance date of the Series B Preferred Stock, the holders of the Series B Preferred Stock would be entitled to require us to settle their shares of Series B Preferred Stock for cash at a price per share equal to the fair value of the Series B Preferred Stock at such time as described in the Certificate of Designation or Preferences, Rights and Limitations of the Series B Preferred Stock. If we are forced to cash settle a significant amount of the shares of our common stock underlying the Series B Preferred Stock, it could materially affect our results of operations, business and financial condition. We cannot assure you that we will be able to meet Nasdaq's initial listing standards. Furthermore, if we fail to obtain approval of the Nasdaq Listing Application, we may be unable to execute on our plans for the Company following the Acquisition, which could materially affect our results of operations, business and financial condition.

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

In February 2026, we consummated the Acquisition, pursuant to which we acquired Faeth, and we closed the 2026 Private Placement. We cannot guarantee that implementing the Acquisition and related transactions will not impair stockholder value or otherwise adversely affect our business. The Acquisition poses significant integration

challenges between our businesses and employees which could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of the Acquisition to our stockholders.

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

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

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

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

General Risk Factors

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

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

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

In addition, our preclinical studies and clinical trials may be affected by health epidemics. Clinical site initiation, patient enrollment and activities that require visits to clinical sites, including data monitoring, may be delayed due to prioritization of hospital resources toward the pandemic or concerns among patients about participating in clinical trials during a pandemic. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. These challenges

may also increase the costs of completing our clinical trials. Similarly, if we are unable to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure or experience additional restrictions by their institutions, city or state, our clinical trial operations could be adversely impacted.

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

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

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some threat actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to computer viruses, malicious or unintentional actions or inactions that cause vulnerabilities, malware, software or hardware failure, supply chain attacks, social engineering (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing), credential stuffing, ransomware, unauthorized access, attacks enhanced or facilitated by artificial intelligence, or AI, natural disasters, terrorism, war and telecommunication and electrical failures. In particular, ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe, and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Future or past business transactions (such as acquisitions or mergers) expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, and other threats to our business operations. For example, we rely on third parties to operate critical business systems and process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, personnel email, and other functions. We also rely on third parties, including CROs, clinical trial sites and clinical trial vendors, to collect, store, and

transmit sensitive data as part of our research activities. Our ability to monitor these third parties is limited, and these third parties may not have adequate information security measures. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover damages, or we may be unable to recover such awards. Supply-chain attacks have also increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

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

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities, including on a timely basis. Further, we have and may in the future experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

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

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

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

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

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Additionally, we cannot be certain that our insurance coverage will be adequate for data security liabilities actually incurred, will continue to be available to us on economically and commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim.

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

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

In the ordinary course of business, we process personal data and other sensitive information. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state and local governments have enacted numerous privacy and data security laws, including federal and state health information privacy laws, federal and state security breach notification laws, federal and state consumer protection laws, and other similar laws (e.g., wiretapping laws). For example, at the federal level, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, many states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services if we become subject to these laws. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act ("CCPA") applies to personal data of consumers, business representatives, and employees who are California residents and requires businesses subject to the CCPA to provide specific disclosures in privacy notices and respond to requests of such individuals to exercise certain rights concerning their personal data. The CCPA provides fines for noncompliance and a limited private right of action in connection with certain data breaches. While the CCPA and other U.S. state comprehensive consumer privacy laws exempt certain personal data processed in connection with clinical trials, these developments could further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work should we become subject to these laws. Similar laws have been passed or are being considered in several other states, as well as at the federal and local levels, and we expect more governments to pass similar laws in the future. The evolving patchwork of local, state and federal privacy and data security laws increases the cost and complexity of operating our business and increases our exposure to liability, including from third party litigation and regulatory investigations, enforcement, fines, and penalties.

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

We increasingly use artificial intelligence and machine learning tools across our operations and business functions, and we expect our use of such tools to expand over time. While we believe that the responsible use of AI tools can enhance our operational efficiency, these tools present risks that could adversely affect our business. AI-generated outputs may be inaccurate, incomplete, or misleading, and reliance on such outputs without adequate human oversight could result in errors in regulatory submissions, clinical or scientific analyses, contractual provisions, or public disclosures. In addition, the input of proprietary, confidential, or sensitive information into

third-party AI platforms could result in the inadvertent disclosure of trade secrets, attorney-client privileged materials, or material nonpublic information. The regulatory landscape governing the use of AI in the life sciences and pharmaceutical industries is rapidly evolving, and new laws, regulations, or guidance — including those arising from the current administration's policy initiatives — could impose additional compliance obligations, restrict certain uses of AI tools, or increase our exposure to regulatory enforcement actions or litigation. Any failure to adequately govern our use of AI tools could result in reputational harm, regulatory scrutiny, or legal liability. In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Additionally, the U.S. Department of Justice issued a rule entitled Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restrictions on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or are considered "foreign persons" and majority owned by, organized under the laws of, primarily resident in, or a contractor of a covered person or country of concern, as applicable) that impacts certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

In addition to data privacy and security laws, we are and may in the future become bound by contractual obligations and industry standards related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies and other statements regarding data privacy and security. Regulators are increasingly scrutinizing these statements, and if these statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

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

Although we endeavor to comply with applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we

rely may fail to comply with such obligations, which could negatively impact our business operations. If we (or third parties with whom we work) fail, or are perceived to have failed, to address or comply with data privacy, protection and security obligations, we could face significant consequences, including (without limitation): government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; and/or imprisonment of company officials. In particular, plaintiffs have become increasingly active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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

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

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

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

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have established policies and processes designed for assessing, identifying, and managing material risk from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including clinical trial data, intellectual property, confidential information that is proprietary, strategic, financial or competitive in nature, and personal data.

Our legal team as well as the Vice Presidents of Product and Engineering are responsible for identifying, assessing and managing the Company’s cybersecurity threats and risks. These functions use various methods such as automated tools, reports of threats and threat actors, third-party threat assessments, and vulnerability assessments in an effort to identify, monitor and assess cybersecurity threats.

Depending on the environment, system and data, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats, including, for example, cybersecurity testing and cybersecurity awareness training, encryption of certain data, network security controls, data segregation, access controls, asset management processes, and systems monitoring tools.

We retain third-party service providers in an effort to help identify, assess and manage the Company's cybersecurity threats and risks, including for example, professional services firms (such as outside legal counsel) and cybersecurity consultants.

We use third-party service providers to perform a variety of functions throughout our business, including, for example, application providers, hosting companies, contract research organizations, and contract manufacturing organizations. Depending on the nature of the services provided, the sensitivity of the systems and data at issue, and the identity of the provider, our vendor engagement processes may include risk assessments, security evaluations, audit requirements, and imposition of cybersecurity obligations.

We have integrated our assessment and management of material risks from cybersecurity threats into our overall risk management systems and processes. For example, our senior management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the board or the board's audit committee which evaluates our overall enterprise risks.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including the risk entitled "If our information systems or data, or those of our collaborators, contractors, consultants or other third parties with whom we work, are or were compromised, we could experience adverse consequences, including but not limited to regulatory investigations or actions; litigation; fines and penalties; significant disruption of our product development programs and our ability to operate our business effectively; reputational harm; and other adverse consequences."

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our Vice President of Engineering, Vice President of Product, and General Counsel integrate cybersecurity risk considerations into the Company's overall risk management strategy, communicate key priorities to relevant personnel, help prepare for cybersecurity incidents, approve cybersecurity processes, and review security assessments and other security-related reports.

Our Vice President of Engineering has approximately 15 years of experience in healthcare technology, including prior roles at Flatiron Health and Epic Systems involving systems that process sensitive patient data. He has expertise in designing and operating systems subject to HIPAA and SOC 2 compliance requirements, including security architecture review, access control and authentication design, and participation in SOC 2 and HIPAA audit and incident response processes.

Our Vice President of Product has over 20 years of experience delivering products across the healthcare ecosystem, including digital health products used in clinical trial management and pharmaceutical ordering. He has experience managing products subject to HIPAA and 21 CFR Part 11 regulatory requirements and maintains training related to HIPAA, data privacy, and security practices in regulated healthcare environments.

Our General Counsel oversees the Company's cybersecurity incident response processes and evaluates cybersecurity risks in the context of SEC disclosure obligations. He has prior experience advising public and private companies on regulatory compliance and risk management, including matters involving data privacy and information security.

Our cybersecurity incident response processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our General Counsel. The General Counsel works with the Company's incident responders in an effort to help mitigate and remediate cybersecurity incidents of

which he is notified. In addition, our incident response processes include reporting to our disclosure committee and audit committee of the board of directors for certain cybersecurity incidents.

Our audit committee receives periodic reports from management concerning the Company's significant cybersecurity threats and risks and the processes designed to address them. The audit committee also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties.

We have leased office and laboratory space in Boston, Massachusetts pursuant to a lease that expires in September 2026. We also lease office and laboratory space in Rockville, Maryland at 1405 Research Blvd, Suite 125, which serves as our principal executive office. The Rockville research operations were wound down in connection with the 2024 Restructuring, and the space is currently used on a limited basis for administrative purposes. The lease expires in 2027. We believe that our current facilities are adequate to meet our ongoing needs, and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may become involved in other litigation or legal proceedings relating to claims arising from the ordinary course of business.

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.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends, if any, 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. Our future ability to pay cash dividends on our capital stock may also be limited by the terms of any future debt or preferred securities or future credit facility.

Stockholders

Our common stock is listed on the Nasdaq Capital Market under the symbol "SNSE". As of March 23, 2026, we had 1,340,281 shares of common stock outstanding held by 193 holders of record. 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.

Use of Proceeds from Initial Public Offering of Common Stock

Not applicable.

Recent Sales of Unregistered Securities

On February 17, 2026, we completed the Acquisition pursuant to the Merger Agreement. In connection with the closing of the Acquisition, we issued to the stockholders of Faeth HoldCo an aggregate of 10,497.0980 shares of our Series B Non-Voting Convertible Preferred Stock. Each share of Series B Preferred Stock is convertible into 1,000 shares of our common stock, representing 10,497,098 shares on an as-converted-to-common-stock basis (without giving effect to any beneficial ownership limitations), subject to stockholder approval of the Company Stockholder Matters and certain beneficial ownership limitations established by each holder. The shares of Series B Preferred Stock issued as Acquisition consideration were offered and sold in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

On February 20, 2026, we completed a private placement of 14,440.395 shares of our Series B Preferred Stock at a purchase price of approximately $13,850 per share (or approximately $13.85 per share on an as-converted-to-common-stock basis) for aggregate gross proceeds of approximately $200 million. The investors in the 2026 Private Placement included B Group Capital, Balyasny Asset Management, Columbia Threadneedle Investments, Cormorant Asset Management, Fairmount, Logos Capital, RA Capital Management, Vivo Capital and other institutional investors. The Series B Preferred Stock issued in the 2026 Private Placement was offered and sold in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder, as a transaction by an issuer not involving a public offering. Each of the investors represented that it was an "accredited investor" as defined in Regulation D and acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof.

Subject to stockholder approval of the Company Stockholder Matters, each share of Series B Preferred Stock will automatically convert into 1,000 shares of common stock, subject to certain beneficial ownership limitations established by each holder; provided that such beneficial ownership limitations may be waived by each holder of Series B Preferred Stock at any time following the approval by Nasdaq of the Nasdaq Listing Application

and approval of the Company Stockholder Matters upon notice to the Company. We have agreed to file a registration statement on Form S-3 to register the resale of shares of common stock issuable upon conversion of the Series B Preferred Stock within 75 calendar days following the closing of the 2026 Private Placement.

For additional information regarding the Acquisition and the 2026 Private Placement, see the Current Report on Form 8-K filed with the SEC on February 18, 2026 and Note 15 to the consolidated financial statements included elsewhere in this Annual Report.

Purchases of Equity Securities by the Issuer and Affiliated Parties

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 consolidated financial statements and the related notes and other financial information included elsewhere in this Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

In this section, we discuss our financial condition, changes in financial condition and results of our operations for the year ended December 31, 2025, compared to the year ended December 31, 2024. For a discussion and analysis comparing our results for the year ended December 31, 2024, to the year ended December 31, 2023, see our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 28, 2025, under Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Unless otherwise indicated, all information in this Annual Report on Form 10-K gives effect to a 1-for-20 reverse stock split of our common stock that became effective on June 16, 2025 (the "Reverse Stock Split"), and all references to historical share and per share amounts give effect to the Reverse Stock Split.

Overview

We are a clinical-stage biotechnology company focused on improving outcomes for cancer patients through multi-node inhibition of critical oncogenic pathways. On February 17, 2026, we completed the Acquisition of Faeth Therapeutics, a clinical-stage biotechnology company developing multi-node therapies targeting tumor metabolism and signaling, and received $200 million in gross proceeds from the 2026 Private Placement from a broad syndicate of institutional investors. The acquisition brought Faeth's lead asset, PIKTOR, a proprietary investigational all-oral combination of serabelisib and sapanisertib that inhibits multiple nodes of the PI3K/AKT/mTOR pathway, into our pipeline. Because the Acquisition and 2026 Private Placement closed subsequent to the balance sheet date, the consolidated financial statements included in this Report reflect only the pre-acquisition operations of Sensei Biotherapeutics. For additional information regarding the terms of the acquisition and the concurrent financing, see Note 15 to the consolidated financial statements.

Following the acquisition, our lead program is PIKTOR, an oral multi-node inhibitor of the PI3K/AKT/mTOR pathway in development for endometrial and breast cancer. The PI3K/AKT/mTOR pathway is dysregulated in up to 50% of all solid tumors, making it one of the most prevalent therapeutic targets in oncology. Our core thesis is that simultaneously suppressing multiple pathway nodes can produce deeper, more durable tumor suppression than approved therapies that target only a single node. PIKTOR is currently being evaluated in an ongoing Phase 2 trial in second-line advanced endometrial cancer (Study FTH-PIK-201), with topline data anticipated by year-end 2026, and we intend to initiate a Phase 1b trial in HR+/HER2- advanced breast cancer (Study FTH-PIK-101) by the first half of 2026. We believe the $200 million in financing proceeds, together with our existing cash and cash equivalents, will be sufficient to fund operations through these key clinical milestones.

Prior to the Acquisition, we were primarily focused on the development of solnerstotug (formerly SNS-101), our conditionally active monoclonal antibody targeting the immune checkpoint VISTA. In November 2025, our Board of Directors approved a reduction in force of approximately 65% of our pre-acquisition workforce, referred to herein as the 2025 Restructuring, to preserve capital while we evaluated strategic alternatives, including the Acquisition. We are completing the remaining portions of the solnerstotug Phase 1/2 trial with patients currently on study.

We have incurred significant operating losses since our inception and expect to continue to incur losses for the foreseeable future. Our net loss was $21.1 million and $30.2 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $283.1 million and cash, cash equivalents and marketable securities of $21.2 million, which does not include the $200 million in gross proceeds received in the February 2026 Private Placement. The decrease in our net loss in 2025 was primarily attributable to reduced research and development spending resulting from the wind-down of our legacy programs, together with the 2024 Restructuring and the 2025 Restructuring. We expect our research and development expenses to increase significantly in future periods as we advance the clinical development of PIKTOR and other candidates acquired in the Acquisition. We also expect to incur increased general and administrative expenses related to the integration of

Faeth's operations and the support of our expanded product pipeline. We have not generated any product revenue and do not expect to do so for the foreseeable future, if ever.

Components of Our Results of Operations

Operating Expenses

Research and Development Expense

Our research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates. These expenses include:

- expenses incurred under agreements with CROs, as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;
- the cost of manufacturing our product candidates including the cost of CMOs that manufacture product for use in our preclinical studies and clinical trials and perform analytical testing, scale-up and other services in connection with our development activities;
- the cost of outsourced professional scientific development services;
- employee-related expenses, including salaries, benefits and stock-based compensation for employees engaged in the research and development function;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- fees for maintaining licenses and other amounts due under our third party licensing agreements;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses for utilities and other facility-related costs.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

Our direct external research and development expenses consist primarily of third party costs, such as fees paid to CROs, CMOs, research/testing laboratories and outside consultants in connection with our preclinical development, process development, manufacturing and clinical development activities. We do not allocate these costs to specific product candidates because many of them are deployed across several of our development programs and, as such, are not separately classified. We have historically used internal resources primarily to conduct research and manage our preclinical development, process development, manufacturing and clinical development activities. These employees have worked across multiple development programs and, therefore, we have not historically tracked their costs by program and, as such, are not separately classified. 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. As a result of the Acquisition in February 2026, we generally expect that our research and development expenses will increase as we initiate and advance clinical development of PIKTOR and other candidates acquired.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the scope, progress, outcome and costs of our preclinical studies, our current product candidates and any other product candidates we may acquire or develop;
- manufacturing of our product candidates or making arrangements with third-party manufacturers for both clinical and commercial supplies of these product candidates;

- successful patient enrollment in, and the initiation, duration and completion of clinical trials;
- the cost of gaining regulatory approvals for our product candidates, subject to the successful outcome of ongoing and future clinical trials; and
- the extent of any required post-marketing approval commitments to applicable regulatory authorities.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Product commercialization will take several years and significant additional development costs.

General and Administrative Expense

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel and recruiting expenses. Other general and administrative expenses include facility related costs, patent filing and prosecution costs and professional fees for legal, auditing and tax services, and insurance costs.

We anticipate that our general and administrative expenses will increase due to costs incurred to integrate Faeth's operations and to support the expanded product pipeline. These anticipated increases include higher personnel-related costs as we integrate the Faeth team and the ongoing requirements of managing an expanded clinical-stage pipeline.

Long-Lived Asset Impairment

Our long-lived asset impairments consisted of charges related to the write-down of certain equipment and finance right-of-use assets due to streamlining operations and focusing resources on advancing the clinical development of our former lead product solnerstotug in 2024. There were no long-lived asset impairment charges recorded during the year ended December 31, 2025.

Other Income (Expense)

Our other income (expense) consists of accretion on short-term investments, interest expense and gain or loss on fixed asset disposals.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred or for the research and development tax credits earned in each year, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credit carryforwards will not be realized.

Comparison of Years Ended December 31, 2025 and 2024

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

(in thousands)	For the Twelve Months Ended December 31, 2025	2024	Change
Operating expenses:			
Research and development	$ 10,960	$ 18,627	$ (7,667)
General and administrative	11,328	13,036	(1,708)
Long-lived asset impairment	—	951	(951)
Total operating expenses	22,288	32,614	(10,326)
Loss from operations	(22,288)	(32,614)	10,326
Total other income	1,203	2,457	(1,254)
Net loss	$ (21,085)	$ (30,157)	$ 9,072

Research and Development Expenses

Research and development expenses were $11.0 million for the year ended December 31, 2025, compared to $18.6 million for the year ended December 31, 2024. The decrease of $7.7 million was primarily attributable to $3.1 million of lower personnel costs, including non-cash stock-based compensation and incentives, $1.4 million of lower facilities and equipment cost, $1.1 million less expense relating to lab supply purchases, $0.9 million of lower expense associated with clinical trials, $0.5 million of lower manufacturing cost, $0.4 million less outside research fees, $0.3 million of lower preclinical research expense and $0.2 million of decreased restructuring costs, partially offset by $0.2 million of higher consulting expense.

General and Administrative Expenses

General and administrative expenses were $11.3 million for the year ended December 31, 2025, compared to $13.0 million for the year ended December 31, 2024. The decrease of $1.7 million was primarily attributable to $3.0 million of lower personnel costs, including recruiting, non-cash stock-based compensation and incentives and $0.1 million of lower board fees, partially offset by $1.0 million for higher restructuring costs, $0.3 million of higher consulting cost and $0.1 million higher cost for external administrative fees.

Long-Lived Asset Impairment

Long-lived asset impairment expenses were $1.0 million for the year ended December 31, 2024, related to $0.6 million of financing right-of-use equipment lease impairments and $0.4 million of fixed asset impairments.

Other Income (Expense)

Other income was $1.2 million and $2.5 million for the years ended December 31, 2025 and 2024, respectively, primarily attributable to interest and accretion on investments.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any product revenue and have incurred net losses and negative cash flows from our operations. As of December 31, 2025, we had cash, cash equivalents and marketable securities of $21.2 million. We have financed our operations through sales of our common stock, convertible preferred stock and convertible debt. Through the date of this Report, we have raised an aggregate of $123.4 million of gross proceeds from private placements of our equity and convertible debt securities, net proceeds of $138.5 million from our initial public offering in February 2021 and gross proceeds of $200 million from the 2026 Private Placement completed in February 2026. Our net loss was $21.1 million and $30.2 million for the years ended December 31,

2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $283.1 million. 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.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods below:

	For the Twelve Months Ended December 31,	
(in thousands)	**2025**	**2024**
Net cash used in operating activities	$ (20,453)	$ (24,670)
Net cash provided by investing activities	19,772	22,440
Net cash used in financing activities	(645)	(787)
Net decrease in cash and cash equivalents	$ (1,326)	$ (3,017)

Operating Activities

During the year ended December 31, 2025, our operating activities used $20.5 million of cash, resulting from our $21.1 million net loss and a $1.6 million decrease related to changes in our operating assets and liabilities partially offset by increases in non-cash charges of $2.2 million, primarily related to $1.5 million of non-cash lease expense, $1.3 million of stock compensation expense and $0.1 million of depreciation partially offset by $0.7 million of accretion on marketable securities. During the year ended December 31, 2024, our operating activities used $24.7 million of cash, resulting from our $30.2 million net loss and a $0.5 million decrease related to changes in our operating assets and liabilities partially offset by increases in non-cash charges of $6.0 million primarily related to $3.1 million of stock compensation expense, $1.6 million of non-cash lease expense, $0.8 million of amortization of financing lease right-of-use assets, $0.6 million for financing right-of-use asset impairments, $0.6 million of depreciation and $0.3 million of loss on fixed asset impairments, partially offset by $1.0 million of accretion on marketable securities.

Investing Activities

During the year ended December 31, 2025, net cash provided by investing activities was $19.8 million, primarily due to $44.7 million in maturities of short-term investments and $0.3 million in proceeds from the sale of property and equipment, partially offset by $25.2 million in purchases of short-term investments. During the year ended December 31, 2024, net cash used in investing activities was $22.4 million primarily due to $67.2 million in maturities of short-term investments partially offset by $44.6 million in purchases of short-term investments and $0.2 million in purchases of property and equipment.

Financing Activities

During the year ended December 31, 2025, net cash used in financing activities was $0.6 million, primarily from $0.8 million of principal payments under our financing leases, partially offset by $0.1 million in proceeds from the sale of financing leased assets. During the year ended December 31, 2024, net cash used in financing activities was $0.8 million, consisting of $0.8 million of principal payments under our financing leases.

Material Cash Requirements

Our material cash requirements will have an impact on our future liquidity. Our material cash requirements represent material expected or contractually committed future payment obligations.

Operating Leases

We have operating lease arrangements for our corporate offices, lab facilities and an executive residence. As part of our adoption of Accounting Standards Codification, or ASC, 842, we recorded operating right-of-use assets

and operating lease liabilities for these agreements. As of December 31, 2025, we had operating lease payment obligations of $1.5 million, with $1.4 million payable within twelve months. See Note 6 in our annual financial statements included elsewhere in this Report for additional information.

Finance Leases

We lease research equipment, furniture and a vehicle under finance leases. As part of our adoption of ASC 842, we recorded financing right-of-use assets and financing lease liabilities for these leases as of January 1, 2022. As of December 31, 2025, we had finance lease payment obligations of $0.1 million, with $0.1 million payable within 12 months. See Note 6 in our annual financial statements included elsewhere in this Report for additional information.

In the biopharmaceutical industry, it can take a significant amount of time and capital resources to successfully complete all stages of research and development and commercialize a product candidate. The ultimate length of time and spend required cannot be accurately estimated as it varies substantially according to the type, complexity, novelty and intended use of a product candidate. Please see the “Funding Requirements” section below for further details.

In addition, our future capital requirements will depend on many factors, including, without limitation, the timing of stockholder approval of the Company Stockholder Matters and the potential cash settlement obligations that may arise if we are unable to timely deliver shares of our common stock upon conversion of the Series B Preferred Stock. In connection with the Acquisition, we issued 24,937.493 shares of Series B Preferred Stock, each share of which is convertible into 1,000 shares of our common stock, subject to certain beneficial ownership limitations and receipt of approval of the Company Stockholder Matters. The shares of Series B Preferred Stock will automatically convert upon the third business day following receipt of approval of the Company Stockholder Matters stockholder approval in accordance with Nasdaq listing rules up to the beneficial ownership limitations set by each holder; provided that such beneficial ownership limitations may be waived by each holder of Series B Preferred Stock at any time following the approval by Nasdaq of the Nasdaq Listing Application and approval of the Company Stockholder Matters.

The Certificate of Designation contains a provision that, at any time following the earlier of (i) approval of the Company Stockholder Matters or (ii) six months after the initial issuance of the Series B Preferred Stock, if we fail to deliver shares of our common stock to a converting holder within the time periods required by the Certificate of Designation, such holder may require us to pay, in lieu of delivering the applicable conversion shares, an amount of cash equal to the fair value of the undelivered shares based on the last reported closing sale price of our common stock on the principal trading market on which our common stock is listed as of the trading day immediately prior to the date on which the applicable notice of conversion was delivered to us. Such payment would be required within two business days of the holder's request.

If we are unable to obtain approval of the Company Stockholder Matters or approval of the Nasdaq Listing Application, or if we are otherwise unable to timely deliver shares of our common stock upon conversion — whether due to an insufficient number of authorized shares, Nasdaq listing requirements, or other factors — we could become obligated to make significant cash settlement payments to holders of Series B Preferred Stock who submit conversion notices after the applicable trigger date. Given the number of shares of Series B Preferred Stock outstanding and the potential magnitude of such cash settlement obligations, which would be determined by reference to the then-current trading price of our common stock, any such payments could require us to use a substantial portion of our available cash resources or to seek additional financing to satisfy these obligations, which could materially limit the amount of cash available to fund our operations and advance our clinical programs.

Additionally, even following stockholder approval of the Company Stockholder Matters, certain holders may be unable to convert their shares of Series B Preferred Stock due to the application of beneficial ownership limitations set by such holder. Shares of Series B Preferred Stock that are not converted in the automatic conversion on account of beneficial ownership limitations will remain outstanding until converted at the option of the applicable holder, and the cash settlement provisions described above would apply to any failure to timely deliver conversion shares in connection with any such optional conversion.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of, and potentially seek marketing approval for, our product candidates. In addition, we expect to continue to incur significant costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results of current and future preclinical studies and clinical trials for our current and future product candidates;
- the cost and timing of the manufacture of additional clinical trial material as well as any costs related to the scale-up of manufacturing activities;
- the costs to seek regulatory approvals for any product candidates that successfully complete clinical trials;
- the need to hire additional clinical, quality assurance, quality control and other scientific personnel;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting and maintaining compliance with regulatory requirements;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the terms of any collaboration agreements we may choose to enter into, including the achievement of milestones or occurrence of other developments that trigger payments under any license or collaboration agreements we might have at such time;
- the cost associated with the expansion of our operational, financial and management systems and increased personnel, including personnel to support our operations as a public company; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products, if approved, on our own.

We expect our existing cash and cash equivalents, together with the proceeds from the 2026 Private Placement, will enable us to fund our operating expenses and capital expenditure requirements through topline data readouts from both our ongoing Phase 2 trial of PIKTOR in advanced endometrial cancer (Study FTH-PIK-201) and our planned Phase 1b trial of PIKTOR in HR+/HER2- advanced breast cancer (Study FTH-PIK-101). We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of product discovery, preclinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and

- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

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. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could 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 restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in fixed payment obligations.

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 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.

Critical Accounting Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our financial statements, which are prepared in accordance with US GAAP. The preparation of our financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates.

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are described in Note 2 to our annual financial statements beginning on page F-1 of this Report, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

Accrued Research and Development Expenses

We incur expenses associated with preclinical development and clinical trials. Accounting for preclinical or clinical activities relating to work performed by CROs and other external vendors requires management to exercise significant estimates in regard to the timing and accounting for these expenses. We estimate costs of research and development activities conducted by service providers, which include, the conduct of sponsored research, preclinical studies and contract manufacturing activities. The diverse nature of services being provided under CRO and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain clinical activities complicates the estimation of accruals for services rendered by CROs and other vendors in connection with clinical trials. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in the accrued and other current liabilities or prepaid expenses on the balance sheets and within research and development expense on the consolidated statements of operations. We determine the estimated costs through discussions with the internal personnel and external service providers as to the progress, or stage of completion of the services and the agreed-upon fees to be paid for such services. This process involves a thorough review of open contracts and evaluation by internal personnel to identify services received that have been performed for us and estimating the associated cost incurred for these services for which we have not yet been invoiced or otherwise notified of the actual cost. In estimating the duration of a clinical study, we evaluate the start-up, treatment and

wrap-up periods, compensation arrangements and services rendered attributable to each clinical trial and fluctuations are regularly tested against payment plans and trial completion assumptions.

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that may be used to conduct and manage clinical trials on our behalf. We determine the estimated costs through discussions with internal personnel and external service providers as to the progress, or stage of completion of the services and the agreed-upon fees to be paid for such services. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

Stock-Based Compensation

We measure all stock-based awards granted based on their estimated fair value on the date of the grant and recognize the corresponding compensation expense for those awarded to employees and directors over the requisite service period, which is generally the vesting period of the respective award, and for those awarded to nonemployees over the period during which services are rendered by nonemployees until completed. We have typically issued stock options and warrants with service-based vesting conditions and we record the expense for these awards using the straight-line method.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model, which uses as inputs the closing price of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options and warrants, the risk-free interest rate for a period that approximates the expected term of our stock options and warrants and our expected dividend yield. The fair value of our stock options and warrants on the date of grant, prior to February 3, 2021, was determined by us with the assistance of a third-party valuation specialist in accordance with the guidance in the American Institute of Certified Public Accountants Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, as our common stock was not actively traded.

Recent Accounting Pronouncements

See Note 2 in our annual financial statements included elsewhere in this Report for a description of recent accounting pronouncements applicable to our financial statements. Other than as disclosed in our financial statements, we do not expect that any recently issued accounting standards will have a material impact on our financial statements or will otherwise apply to our operations.

Emerging Growth Company and Smaller Reporting Company Status

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

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of our initial public offering or such earlier time that we are no longer an emerging growth company. We would cease to be an EGC earlier if we have more than $1.235 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than $1.0 billion of non-convertible debt securities over a three-year period. For so long as we remain an EGC, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. We may choose to take advantage of some, but not all, of the available exemptions.

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

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 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 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million.

If we are a smaller reporting company at the time we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to EGCs, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer, or PEO, and Principal Financial Officer, or PFO, evaluated the effectiveness 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. Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our PEO and PFO, as appropriate to allow timely decisions regarding required disclosures, and is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Based on this evaluation, our PEO and PFO have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2025.

Management's Report on Internal Control over Financial Reporting and Attestation Report of the Registered Public Accounting Firm

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting, as defined in the Exchange Act Rule 13a-15(f). 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. Based on the assessment, management concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

This Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting as required by Section 404(b) of the Sarbanes Oxley Act of 2002. Because we qualify as an emerging growth company under the JOBS Act, management's report was not subject to attestation by our independent registered public accounting firm.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2025, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

Rule 10b5-1 Trading Plans

During the fiscal quarter ended December 31, 2025, none of our officers or directors, as defined in Rule 16a-1(f), adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

Elimination of Series A Preferred Stock

As previously reported, on March 7, 2023, the Special Committee of the Board of Directors of the Company adopted a stockholder rights plan and declared a dividend of one right, or a Right, for each outstanding share of common stock of the Company. Each Right entitled the registered holder thereof under certain circumstances to purchase from the Company one ten-thousandth of a share of Series A Junior Participating Cumulative Preferred Stock. The terms of the Rights were set forth in a Stockholder Rights Agreement, dated as of March 7, 2023, between the Company and American Stock Transfer & Trust Company, LLC, as rights agent, or, as amended, the Rights Agreement.

The Rights expired pursuant to the terms of the Rights Agreement on March 7, 2025. Accordingly, on March 26, 2025, the Company filed with the Secretary of State of the State of Delaware a Certificate of Elimination eliminating from its Amended and Restated Certificate of Incorporation, as amended, the designation of certain shares of its preferred stock as Series A Junior Participating Cumulative Preferred Stock, which had been designated for potential use in connection with the Rights Agreement. As a result, all shares of preferred stock previously

designated as Series A Junior Participating Cumulative Preferred Stock were eliminated and returned to the status of authorized but unissued shares of preferred stock, without designation.

The foregoing description of the Certificate of Elimination does not purport to be complete and is subject to and qualified in its entirety by reference to the full text of the Certificate of Elimination, which is included as Exhibit 3.4 hereto, and is incorporated by reference herein.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

PART III

We will file a definitive Proxy Statement for our 2026 Annual Meeting of Stockholders, or the 2026 Proxy Statement, with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2026 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by Item 10 is hereby incorporated by reference to the sections of the 2026 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Election of Directors," "Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance."

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at www.senseibio.com. The Audit Committee is responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for executive officers and directors. If we make any substantive amendments to the Code of Conduct or grant any waiver from a provision of the Code of Conduct to any executive officer or director, we will promptly disclose the amendment or waiver on our website.

Insider Trading Policy

We have adopted an insider trading policy governing the purchase, sale, and other dispositions of our securities and those of public companies in which we have business dealings by our directors, executive officers, employees and consultants, that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations, and the exchange listing standards applicable to us. This policy also prohibits directors, officers, and other employees from engaging in short sales, transactions in put or call options, hedging transactions, margin accounts or other inherently speculative transactions with respect to our stock at any time. In addition, it is the Company's intent to comply with applicable laws and regulations relating to insider trading. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required by Item 11 is hereby incorporated by reference to the sections of the 2026 Proxy Statement under the captions "Executive Compensation" and "Non-Employee Director Compensation."

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by Item 12 is hereby incorporated by reference to the sections of the 2026 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans."

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by Item 13 is hereby incorporated by reference to the sections of the 2026 Proxy Statement under the captions "Transactions with Related Persons" and "Independence of the Board of Directors."

Item 14. Principal Accounting Fees and Services.

The information required by Item 14 is hereby incorporated by reference to the sections of the 2026 Proxy Statement under the caption "Ratification of Selection of Independent Registered Public Accounting Firm."

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Exhibits

Exhibit Number	Description
2.1‡	Agreement and Plan of Merger, dated February 17, 2026, by and among Sensei Biotherapeutics, Inc., Sapphire First Merger Sub, Inc., Sapphire Second Merger Sub, LLC, Faeth Holdings Therapeutics, Inc. and Faeth Therapeutics, LLC (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on February 18, 2026)
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on February 11, 2021).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on December 9, 2022).
3.3	Certificate of Designations of the Series A Junior Participating Cumulative Preferred Stock of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on March 7, 2023).
3.4	Certificate of Elimination of the Series A Junior Participating Cumulative Preferred Stock of the Registrant (incorporated by reference to Exhibit 3.4 to the Registrant's Annual Report on Form 10-K (File No. 001-39980), filed with the SEC on March 28, 2025).
3.5	Certificate of Designation of Series B Non-Voting Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on February 18, 2026)
4.1*	Description of Securities.
4.2‡*	Warrant to Purchase Stock, dated as of September 7, 2021, by and between Faeth Therapeutics, Inc. and Western Alliance Bank.
10.1#	Form of Indemnification Agreement entered into by and between Sensei Biotherapeutics, Inc. and each director and executive officer (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.2	Sensei Biotherapeutics, Inc. 2018 Equity Incentive Plan, as amended, and forms of agreements thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.3	Sensei Biotherapeutics, Inc. 2021 Equity Incentive Plan and forms of agreements thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.4	Sensei Biotherapeutics, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.5	Form of Stock Option Grant Notice and Stock Option Agreement for Inducement Grants Outside of the Sensei Biotherapeutics, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on February 18, 2026).
10.6#*	Faeth Therapeutics, Inc. 2019 Stock Incentive Plan and forms of agreements thereunder.
10.7#	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K (File No. 001-39980) filed with the SEC on March 15, 2022).
10.8	Lease Agreement, by and between Sensei Biotherapeutics, Inc. and Are-Maryland No. 8 Corp., dated as of October 22, 2020 (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.9	Lease Agreement, by and between Sensei Biotherapeutics, Inc. and RREF II 451D, LLC, dated as of January 13, 2021 (incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K (File No. 001-39980) filed with the SEC on March 15, 2022).

10.10#*	Employment Agreement, dated July 31, 2024, by and between the Registrant and Christopher Gerry
10.11#	Employment Agreement dated July 12, 2024, by and between the Registrant and Josiah Craver (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39980) filed with the SEC on November 11, 2024).
10.12#	Employment Letter between the Company and Anand Parikh, effective February 17, 2026 (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on February 18, 2026)
10.13#	Form of Consulting Agreement, dated November 14, 2025, entered into with John Celebi, Edward van der Horst and Stephanie Krebs. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39980) filed with the SEC on November 14, 2025).
10.14*	Amended Retention Agreement, dated as of February 17, 2025, entered into with Christopher Gerry.
10.15*	Amended Retention Agreement, dated as of February 17, 2025, entered into with Josiah Craver.
10.16	Open Market Sales Agreement[SM], dated March 15, 2022, by and between the Registrant and Jefferies LLC (incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-3 (File No. 333-263567), filed with the SEC on March 15, 2022).
10.17‡	Form of Securities Purchase Agreement, dated as of February 17, 2026, by and among Sensei Biotherapeutics, Inc. and each investor listed on Exhibit A thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on February 18, 2026)
10.18	Form of Registration Rights Agreement, by and among Sensei Biotherapeutics, Inc. and certain investors signatory thereto (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on February 18, 2026)
10.19†*	Exclusive License Agreement, dated as of August 10, 2007, between Faeth Therapeutics, Inc. (as successor in interest to Calithera Biosciences, Inc., Millennium Pharmaceuticals, Inc. and Intellikine, Inc.) and The Regents of the University of California and acting through its Office of Technology Management, University of California San Francisco, as amended by Amendment No. 1 dated as of March 13, 2009, Amendment No. 2 dated as of July 8, 2009, Amendment No. 3 dated as of November 30, 2010, Amendment No. 4 dated September 8, 2014, Amendment No. 5 dated August 4, 2021, and Amendment No. 6 dated as of February 1, 2022.
10.20†*	License Agreement, dated as of March 18, 2019, between Faeth Therapeutics, Inc. (as successor in interest to Petra Pharma Corporation and Ravenna Pharmaceuticals, Inc.) and Takeda Pharmaceutical Company Limited.
10.21†*	Amended and Restated TAK-228 Asset Purchase Agreement, dated as of May 15, 2023, between Faeth Therapeutics, Inc. (as successor in interest to Calithera Biosciences, Inc.) and Millennium Pharmaceuticals, Inc.
10.22†*	Letter Agreement, dated as of May 15, 2023, between Millennium Pharmaceuticals, Inc. and Faeth Therapeutics, Inc.
10.23†*	Letter Agreement dated as of January 29, 2026, between Millennium Pharmaceuticals, Inc., Takeda Pharmaceutical Company Limited and Faeth Therapeutics, Inc.
10.24*	Retention Agreement, dated as of December 22, 2025, entered into with Christopher Gerry.
10.25*	Retention Agreement, dated as of December 22, 2025, entered into with Josiah Craver.
19.1	Insider Trading Policy(incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K (File No. 001-39980), filed with the SEC on March 28, 2025).
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting firm.
24.1*	Power of Attorney (included on signature page).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

97.1	Incentive Compensation Recoupment Policy, adopted on October 2, 2023 (incorporated by reference to Exhibit 97 to the Registrant's Annual Report on Form 10-K (File No. 001-39980) filed with the SEC on February 29, 2024).
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed herewith.
** This certification is being furnished solely to accompany this Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
# Indicates management contract or compensatory plan.
† Pursuant to Item 601(b)(10) of Regulation S-K, portions of this exhibit (indicated by asterisks) have been omitted as the registrant has determined that the omitted information is (i) not material and (ii) the type of information that the registrant customarily and actually treats as private or confidential.
‡ Certain schedules, annexes and attachments have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant agrees to provide, on a supplemental basis, a copy of any omitted schedules, annexes and attachments to the SEC or its staff upon request.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Sensei Biotherapeutics, Inc.

Date: March 30, 2026

By: /s/ Christopher W. Gerry
Christopher W. Gerry
President and General Counsel

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Christopher W. Gerry and Josiah Craver, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of Sensei Biotherapeutics, Inc., and any or all amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Christopher W. Gerry **Christopher W. Gerry**	President and General Counsel (*Principal Executive Officer*)	March 30, 2026
/s/ Josiah Craver **Josiah Craver**	Senior Vice President of Finance (*Principal Financial and Accounting Officer)*	March 30, 2026
/s/ Bob Holmen **Bob Holmen**	Director	March 30, 2026
/s/ Thomas Ricks **Thomas Ricks**	Director	March 30, 2026
/s/ Kristian Humer **Kristian Humer**	Director	March 30, 2026
/s/ Phillip Donenberg **Phillip Donenberg**	Director	March 30, 2026
/s/ Anand Parikh **Anand Parikh**	Director	March 30, 2026

SENSEI BIOTHERAPEUTICS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Sensei Biotherapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Sensei Biotherapeutics, Inc. and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, common stock and 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 as of 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 accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company may be required to make significant cash payments to holders of Series B Non-Voting Convertible Preferred Stock that could substantially reduce the Company’s available cash resources which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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.

/s/ Deloitte & Touche LLP

Baltimore, Maryland

March 30, 2026

We have served as the Company’s auditor since 2016.

SENSEI BIOTHERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 8,668	$ 9,994
Marketable securities	12,516	31,341
Prepaid expenses	231	474
Other current assets	92	120
Total current assets	21,507	41,929
Right-of-use assets - operating leases, net	1,294	2,804
Right-of-use assets - financing leases, net	1	163
Property and equipment, net	82	417
Other non-current assets	18	48
Total assets	$ 22,902	$ 45,361
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 1,481	$ 1,248
Compensation and employee benefits liabilities	1,320	1,882
Operating lease liabilities, current	1,370	1,586
Financing lease liabilities, current	80	732
Total current liabilities	4,251	5,448
Operating lease liabilities, non-current	59	1,429
Financing lease liabilities, non-current	—	98
Total liabilities	$ 4,310	$ 6,975
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.0001 par value and 10,000,000 shares authorized as of December 31, 2025 and December 31, 2024; zero shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	—	—
Common stock, $0.0001 par value and 12,500,000 shares authorized as of December 31, 2025 and December 31, 2024; 1,261,685 and 1,258,940 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	301,728	300,451
Accumulated deficit	(283,137)	(262,052)
Accumulated other comprehensive loss	1	(13)
Total stockholders' equity	18,592	38,386
Total liabilities and stockholders' equity	$ 22,902	$ 45,361

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

SENSEI BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	For the Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 10,960	$ 18,627
General and administrative	11,328	13,036
Long-lived asset impairment	—	951
Total operating expenses	22,288	32,614
Loss from operations	(22,288)	(32,614)
Other income (expense):		
Interest income	1,239	2,550
Interest expense	(32)	(90)
Other expense, net	(4)	(3)
Net loss	(21,085)	(30,157)
Net loss per common share, basic and diluted	$ (16.72)	$ (24.01)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	1,260,772	1,255,776
Comprehensive loss:		
Net loss	$ (21,085)	$ (30,157)
Other comprehensive items:		
Unrealized gain on marketable securities	14	196
Total other comprehensive income	14	196
Total comprehensive loss	$ (21,071)	$ (29,961)

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

SENSEI BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF COMMON STOCK AND STOCKHOLDERS' EQUITY
(In thousands, except share data)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other	Total Stockholders'
	Shares	Amount	Capital	Deficit	Comprehensive Loss	Equity
Balance at December 31, 2023	1,251,432	$ —	$ 296,999	$ (231,895)	$ (209)	$ 64,895
Stock-based compensation expense	—	—	3,135	—	—	3,135
Issuance of equity in exchange for compensation	—	—	293	—	—	293
Surrender of shares for tax withholding	(616)	—	(10)	—	—	(10)
Vesting of restricted stock shares	4,498	—	—	—	—	—
Employee stock purchase plan expense	3,626		34	—	—	34
Unrealized gain on marketable securities	—	—	—	—	196	196
Net loss	—	—	—	(30,157)	—	(30,157)
Balance at December 31, 2024	1,258,940	$ —	$ 300,451	$ (262,052)	$ (13)	$ 38,386
Stock-based compensation expense	—	—	1,274	—	—	1,274
Surrender of shares for tax withholding	(390)	—	(3)	—	—	(3)
Vesting of restricted stock shares	1,768	—	—	—	—	—
Employee stock purchase plan expense	1,004	—	5	—	—	5
Cash-in-lieu of fractional shares for reverse stock split	(32)	—	(1)	—	—	(1)
Exercise of stock options into common stock	395	—	2	—	—	2
Unrealized gain on marketable securities	—	—	—	—	14	14
Net loss	—	—	—	(21,085)	—	(21,085)
Balance at December 31, 2025	1,261,685	-	301,728	(283,137)	1	18,592

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

SENSEI BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	For the Year Ended December 31,	
	2025	**2024**
Operating activities		
Net loss	$ (21,085)	$ (30,157)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,274	3,135
Depreciation and amortization	122	551
Accretion on marketable securities	(699)	(986)
Impairment of financing right-of-use asset assets	—	609
Impairment of equipment	—	342
Non-cash lease expense	1,510	1,554
Amortization of financing lease right-of-use assets	17	771
Changes in operating assets and liabilities:		
Prepaid expenses	243	694
Other assets	80	244
Accounts payable and accrued liabilities	233	(445)
Compensation and employee benefits	(562)	666
Operating lease liabilities	(1,586)	(1,581)
Other liabilities	—	(67)
Net cash used in operating activities	(20,453)	(24,670)
Investing activities		
Purchases of property and equipment	(16)	(146)
Purchases of short-term investments	(25,155)	(44,595)
Maturities of short-term investments	44,693	67,181
Proceeds from sale of property and equipment	250	—
Net cash provided by investing activities	19,772	22,440
Financing activities		
Principal payments for financing leases	(790)	(811)
Proceeds from the sale of financing lease assets	142	—
Payment of employee restricted stock tax withholdings	(3)	(10)
Employee stock purchase plan proceeds	5	34
Cash in lieu of fractional shares for reverse stock split	(1)	—
Exercise of options into common stock	2	—
Net cash used in financing activities	(645)	(787)
Net decrease in cash and cash equivalents	(1,326)	(3,017)
Cash and cash equivalents at beginning of period	9,994	13,011
Cash and cash equivalents at end of period	$ 8,668	$ 9,994
Supplemental disclosure of noncash financing information:		
Issuance of equity in exchange for compensation included in compensation and employee benefits	$ —	$ 293
Initial measurement of operating lease right-of-use assets	$ —	$ 28
Initial measurement of operating lease liabilities	$ —	$ 28
Initial measurement of finance lease right-of-use assets	$ —	$ 1

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

SENSEI BIOTHERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION AND OPERATIONS

Business

Sensei Biotherapeutics, Inc. (the "Company" or "Sensei"), a clinical-stage biotechnology company, was incorporated in 1999 as a Maryland corporation until being incorporated in Delaware on December 1, 2017. The Company is focused on the discovery and development of next-generation therapeutics for cancer patients.

Liquidity and capital resources

Since its inception, the Company has devoted substantially all of its resources to advancing development of its portfolio of programs, establishing and protecting its intellectual property, conducting research and development activities, organizing and staffing the Company, business planning, raising capital and providing general and administrative support for these operations. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, technical risks associated with the successful research, development and manufacturing of product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Current and future programs will require significant 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 and infrastructure. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Since its inception, the Company has incurred substantial losses and had a net loss of $21.1 million for the year ended December 31, 2025. As of December 31, 2025, the Company had an accumulated deficit of $283.1 million. The Company expects to generate operating losses and negative operating cash flows for the foreseeable future.

The Company will need additional financing to support its continuing operations and pursue its current strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. The Company may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. The inability to raise capital as and when needed would have a negative impact on the Company's financial condition and its ability to pursue its business strategy. The Company will need to generate significant revenue to achieve profitability, and it may never do so.

As of December 31, 2025, the Company had $21.1 million of cash, cash equivalents and marketable securities. In February 2026, the company completed a private placement financing through the sale of Series B Non-Voting Convertible Preferred Stock, resulting in gross proceeds of $200 million.

The Series B Preferred Stock is subject to automatic conversion into Common Stock upon the third business day following the Company's receipt of stockholder approval in accordance with Nasdaq listing rules. The Certificate of Designation of Preferences, Rights and Limitations of the Series B Non-Voting Convertible Preferred Stock (the "Certificate of Designation") provides that, at any time following the earlier of (i) stockholder approval or (ii) six months after the initial issuance of the Series B Preferred Stock, if the Company fails to timely deliver shares of Common Stock to a converting holder in accordance with the terms of the Certificate of Designation, such holder may require the Company to pay cash in an amount equal to the fair value of the undelivered shares.

The Company's ability to satisfy these potential cash settlement obligations is not entirely within its control, as it is contingent on, among other things, the Company's ability to obtain stockholder approval and to deliver shares of Common Stock upon conversion within the timeframes required by the Certificate of Designation. If the Company is unable to obtain stockholder approval in a timely manner, or is otherwise unable to timely deliver shares of Common Stock upon conversion, holders who submit conversion notices after the applicable trigger date could require the Company to make significant cash payments that could substantially reduce the Company's available cash resources.

After evaluating the conditions described above in the aggregate, the Company has concluded that there is substantial doubt about its ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on the basis that the Company will continue to operate as a going concern, which contemplates it will be able to realize assets and settle liabilities and commitments in the normal course of business for the foreseeable future. Accordingly, the accompanying consolidated financial statements do not include any adjustments that may result from the outcome of these uncertainties.

Reverse stock split

On June 16, 2025, at 5:00 p.m. Eastern Time, the Company effected a 1-for-20 reverse stock split of the Company's issued and outstanding shares of common stock and a corresponding reduction in the total number of authorized shares of its common stock from 250,000,000 shares to 12,500,000 shares, as authorized at the Company's 2025 annual meeting of stockholders held on May 21, 2025 and approved by the Company's board of directors on June 3, 2025. As a result of the Reverse Stock Split, every 20 shares of issued and outstanding common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value of $0.0001 per share. No fractional shares were issued as a result of the Reverse Stock Split. Stockholders entitled to a fractional share received a cash payment based on the average closing sales price of the Company's common stock on The Nasdaq Stock Market for the five trading days immediately preceding the filing date of the Certificate of Amendment. All historical share and per share amounts reflected throughout the financial statements have been adjusted to reflect the Reverse Stock Split. Proportionate adjustments were made to the per share exercise price and the number of shares of common stock that may be purchased upon exercise of outstanding stock options and warrants, the number of shares of common stock reserved for future issuance under the 2021 Equity Incentive Plan (the "2021 Plan") and the 2021 Employee Stock Purchase Plan (the "2021 ESPP").

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The Company has prepared the accompanying consolidated financial statements in conformity with generally accepted accounting principles in the United States ("US GAAP"). The consolidated financial statements include those accounts of the Company and its subsidiaries after elimination of all intercompany accounts and transactions.

Use of Estimates

The preparation of consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods presented. Estimates are used for, but are not limited to, stock-based compensation, accrued research and development expenses, depreciation of equipment, fair value of financial instruments, the Company's ability to continue as a going concern and contingencies. Actual results may differ from those estimates.

Cash and Cash Equivalents

Cash equivalents are highly liquid investments with an original maturity of 90 days or less at the date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions. As of December 31, 2025, cash and cash equivalents included cash on deposit at commercial banks, and a money market fund that invests in U.S. Government securities.

Marketable Securities

Investments consist of marketable securities with original maturities greater than 90 days at the date of purchase. The Company has classified its investments with maturities beyond one year as short-term, based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations. The Company considers its investment portfolio of marketable securities to be available-for-sale. Accordingly, these investments are recorded at fair value (Level 2). Unrealized gains and losses are reported as the accumulated other comprehensive items in stockholders' equity. Amortization and accretion of premiums and discounts are recorded in other income (expense). Realized gains or losses on debt securities are included in interest income or interest expense, respectively. If any adjustment to fair value reflects a decline in value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is other than temporary and, if so, marks the investment to market on the Company's statement of operations and comprehensive loss.

Balance Sheet Risk

The Company maintains each of its cash, cash equivalents and available-for-sale securities balances with high-quality and accredited financial institutions and accordingly, such funds are not exposed to significant credit risk. Periodically the Company maintains deposits in accredited financial intuitions in excess of the federally insured limits. The Company does not believe that it is subject to the unusual credit risk beyond the normal credit risk associated with the commercial banking relationships.

Leases

At lease inception, the Company determines if an arrangement is or contains a lease, and if so, assesses the lease for classification as either an operating or finance lease. A lease is classified as a finance lease if any one of the following criteria are met: (i) the lease transfers ownership of the asset by the end of the lease term, (ii) the lease contains an option to purchase the asset that is reasonably certain to be exercised, (iii) the lease term is for a major part of the remaining useful life of the asset, (iv) the present value of the lease payments equals or exceeds substantially all of the fair value of the asset, or (v) the leased asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease. A lease is classified as an operating lease if it does not meet any of these criteria.

Leases with a term greater than one year are recognized on the balance sheet as right-of-use ("ROU") assets and current and non-current lease liabilities, as applicable. Leases with a term of one year or less are expensed as rent in the period incurred. The Company elected not to separate lease and non-lease components for all underlying assets. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The incremental borrowing rate is determined by using the rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment. Lease terms include options to extend or terminate the lease when it is reasonably certain that the Company will exercise the options. For leases that existed prior to the adoption of Accounting Standards Update No. 2016-02, Leases (Topic 842) ("ASC 842"), the Company used the remaining lease term to determine the appropriate incremental borrowing rate.

Property and Equipment

Property and equipment are recorded at cost and depreciated or amortized over the estimated useful lives of the assets. Repairs or maintenance costs are expensed as incurred. Depreciation is computed using the straight-line method over the following estimated useful lives:

Office equipment and furniture	3—7 years
Research equipment	1—7 years

Leasehold improvements are depreciated over the shorter of their useful life or the life of the lease.

Fair Value of Financial Instruments

US GAAP requires disclosure of fair value information about financial instruments, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. The framework provides a fair value hierarchy that prioritizes the inputs for the valuation techniques. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements) and minimizes the use of unobservable inputs. The most observable inputs are used, when available. The three levels of the fair value hierarchy are described as follows:

Level 1—Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the Company has the ability to access.

Level 2—Inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; inputs other than quoted prices that are observable for the asset or liability; and inputs that are derived from, or corroborated by, observable market data by correlation or other means.

Level 3—Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment and right of use assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. Impairment losses are then measured by comparing the fair value of assets to their carrying amounts. The Company recorded impairments of $1.0 million for the year ended December 31, 2024, consisting of $0.4 million related to property and equipment and $0.6 million related to right-of-use assets. There were no impairments recorded for the year ended December 31, 2025.

Research and Development Costs

Research and development costs are expensed in the period incurred. Research and development costs include payroll and personnel expense; consulting costs; external contract research and development costs; raw materials and allocated overhead such as depreciation and amortization, rent and utilities. Advance payments for goods and services to be used in future research and development activities are recorded as prepaid expenses and are expensed over the service period as the services are provided or when the goods are consumed.

Clinical trial costs are a component of research and development expenses. The Company estimates expenses incurred for clinical trials that are in process based on services performed under contractual agreements with clinical research organizations and actual clinical investigators. Included in the estimates are (1) the fee per patient enrolled as specified in the clinical trial contract with each institution participating in the clinical trial and (2) progressive data on patient enrollments obtained from participating clinical trial sites and the actual services performed. Changes in clinical trial assumptions, such as the length of time estimated to enroll all patients, rate of screening failures, patient drop-out rates, number and nature of adverse event reports, and the total number of patients enrolled can impact the average and expected cost per patient and the overall cost of the clinical trial. The Company monitors the progress of the trials and their related activities and adjusts, when appropriate, the accruals accordingly. Adjustments to accruals are charged to expense in the period in which the facts that give rise to the adjustment become known. In the event of early termination of a clinical trial or site, the Company would accrue an amount based on estimates of the remaining noncancellable obligations associated with winding down the clinical trial or cancelation of a participating site.

Stock-Based Compensation

The Company accounts for all stock-based compensation, including stock options, restricted stock units and warrants, at fair value and recognizes stock-based compensation expense for those equity awards, net of actual forfeitures, over the requisite service period, which is generally the vesting period of the respective award. Stock-based compensation is classified in the accompanying consolidated statements of operations and comprehensive loss based on the function to which the related services are provided.

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

Income Taxes

Income taxes are accounted for using the asset and liability method of accounting for taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases, including operating loss carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year 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 that includes the enactment date.

A valuation allowance is established when necessary to reduce net deferred tax assets to the amount expected to be realized through future operations. Income tax expense consists of taxes payable for the current period and the net change during the period in deferred tax assets and liabilities.

The Company evaluates its uncertain tax positions based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized. Potential interest and penalties associated with any uncertain tax positions are recorded as a component of income tax expense. Management has evaluated the Company's tax position and concluded that the Company has taken no uncertain tax positions that would require adjustment or disclosure in the consolidated financial statements.

Net Loss Per Share

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated, and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common stock. For purpose of this calculation, outstanding stock options, stock warrants and convertible preferred stock are considered potential dilutive common stock and are excluded from the computation of net loss per share as their effect is anti-dilutive.

The Company's convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive shares of common stock are not assumed to be outstanding if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2025 and 2024.

Segments

The Company manages its operations as a single segment, dedicated to improving outcomes for cancer patients by developing novel therapeutics, including through multi-node inhibition of critical oncogenic pathways. The Company's Chief Operating Decision Maker ("CODM"), the President, reviews the operating results on an aggregate basis and manages the operations as a single operating segment. The CODM oversees performance assessment and resource allocation by reviewing net loss, from our consolidated statement of operations, to guide operational decisions, strategic planning, and forecasting for future periods. To support this oversight, operating expenses are closely tracked to compare budget against actual results. As a single reporting segment, the significant operating expense categories regularly provided to the CODM include research and development, and general and administrative expenses. These expense categories are reported as separate line items in our consolidated statements of operations. All segment assets are reflected as 'total assets' in the consolidated balance sheet. All equipment, leasehold improvements, and fixed assets are located in the United States, and agreements with partners are denominated in U.S. dollars, unless otherwise noted.

Emerging Growth Company Status

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("the JOBS Act"), and may take advantage of reduced reporting requirements that are otherwise applicable to public companies. Section 107 of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with those standards. The Company has elected to use the extended transition period for complying with new or revised accounting standards unless otherwise stated.

The Company will remain an "emerging growth company" until the earliest of (i) December 31, 2026, (ii) the last day of the fiscal year in which it has total annual gross revenues of $1.235 billion or more, (iii) the date on which it has issued more than $1.0 billion in nonconvertible debt during the previous three years or (iv) the date on which it is deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission ("SEC"), which generally is when it has more than $700 million in market value of its stock held by non-affiliates.

Recently Adopted New Accounting Standard

In December 2023, the Financial Accounting Standards Board ("FASB") issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which focuses on the rate reconciliation and income taxes paid. ASU No. 2023-09 requires a public business entity (PBE) to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. For PBEs, the new standard is effective for annual periods beginning after December 15, 2024, with early adoption

permitted. For entities other than PBEs, the requirements will be effective for annual periods beginning after December 15, 2025. An entity may apply the amendments in this ASU prospectively by providing the revised disclosures for the period ending December 31, 2025 and continuing to provide the pre-ASU disclosures for the prior periods, or may apply the amendments retrospectively by providing the revised disclosures for all periods presented. For the year ended December 31, 2025, the Company early adopted this ASU retrospectively. The adoption only impacted the Company's income tax disclosures and had no impact on its results of operations, cash flows, or financial condition.

Recently Issued Accounting Standards

In November 2024, the FASB issued ASU 2024-03, "Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses." The standard is intended to require more detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either prospectively to financial statements issued for reporting periods after the effective date of this ASU or retrospectively to all prior periods presented in the financial statements. The Company is currently assessing the impact this standard will have on its consolidated financial statements.

3. MARKETABLE SECURITIES

Marketable securities consist of the following as of December 31, 2025 and 2024 (in thousands):

	As of December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	$ 9,772	$ 1	$ (1)	$ 9,772
Corporate bonds	2,743	1	—	2,744
Total	$ 12,515	$ 2	$ (1)	$ 12,516

	As of December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	$ 25,875	$ 2	$ (16)	$ 25,861
Corporate bonds	5,479	2	(1)	5,480
Total	$ 31,354	$ 4	$ (17)	$ 31,341

As of December 31, 2025, all marketable securities held by the Company had remaining contractual maturities of one year or less.

There were no impairments of the Company's assets measured and carried at fair value during the year ended December 31, 2025 and 2024.

As of December 31, 2025, an immaterial amount of unrealized losses were associated with marketable securities with contractual maturities of one year or less.

4. FAIR VALUE MEASUREMENTS

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values (in thousands):

	Fair value measurements at December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 7,896	$ —	$ —	$ 7,896
Investments:				
Commercial paper	—	9,772	—	9,772
Corporate bonds	—	2,744	—	2,744
Total	$ 7,896	$ 12,516	$ —	$ 20,412

	Fair value measurements at December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 9,220	$ —	$ —	$ 9,220
Investments:				
Commercial paper	—	25,861	—	25,861
Corporate bonds	—	5,480	—	5,480
Total	$ 9,220	$ 31,341	$ —	$ 40,561

When developing fair value estimates, the Company maximizes the use of observable inputs and minimizes the use of unobservable inputs. When available, the Company uses quoted market prices to measure fair value. The valuation technique used to measure fair value for the Company's Level 1 and Level 2 assets is a market approach, using prices and other relevant information generated by market transactions involving identical or comparable assets. If market prices are not available, the fair value measurement is based on models that use primarily market-based parameters including yield curves, volatilities, credit ratings and currency rates. In certain cases where market rate assumptions are not available, the Company is required to make judgments about assumptions market participants would use to estimate the fair value of a financial instrument.

There were no transfers among Level 1, Level 2 or Level 3 categories in the years ended December 31, 2025 and 2024.

5. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Research equipment	$ —	$ 1,306
Office equipment and furniture	369	354
Leasehold improvement	253	253
Total property and equipment	622	1,913
Less accumulated depreciation and amortization	(540)	(1,496)
Property and equipment, net	$ 82	$ 417

Depreciation and amortization expense for the years ended December 31, 2025 and 2024 was $0.1 million and $0.6 million, respectively.

For the year ended December 31, 2025 the Company disposed of all research equipment through the sale of fixed assets, resulting in a reduction of the gross carrying amount to zero. The related accumulated depreciation of $1.1 million was written off in connection with this disposal. A gain of $42 thousand was recognized on the sale and is included in the other expense line in the consolidated statements of operations and comprehensive loss for the period.

For the year ended December 31, 2024, the Company recorded a charge of $0.4 million in the long-lived asset impairment line in the consolidated statements of operations and comprehensive loss, resulting from streamlining operations and focusing resources on advancing the clinical development of solnerstotug. This charge is comprised of gross write-downs of $0.9 million for research equipment and $0.2 million for office equipment and furniture, and the write-off of associated accumulated depreciation and amortization amounting to $0.6 million and $0.1 million for research equipment and office equipment and furniture, respectively. These amounts were removed from the balance sheet.

6. COMMITMENTS AND CONTINGENCIES

Operating Lease

As of December 31, 2025, the Company leased office and laboratory facilities under operating leases, which expire at various dates through 2027. The Company had $678 thousand in letters of credit outstanding as security on certain of these leases. As part of its adoption of ASC 842, the Company recorded operating right-of-use assets and operating lease liabilities for these leases as of January 1, 2022.

The Company entered into an operating sublease agreement on January 18, 2023 (the "Sublease") with respect to part of its existing Boston office and laboratory facilities (the "Head Lease"). The Company accounted for the Head Lease and the Sublease as separate contracts and there was no effect on the right-of-use asset or lease liability associated with the Head Lease. The Sublease ended on December 31, 2024. The Head Lease rent expense is presented separately from income related to the Sublease and both are reported as components of operating expenses on the consolidated statements of operations and comprehensive loss. The Company recorded $0 and $385 thousand of income related to the Sublease for the years ended December 31, 2025 and 2024, respectively.

Finance Leases

The Company leases research equipment and furniture under finance leases.

The following table contains a summary of the lease costs recognized under ASC 842 pertaining to the Company's finance and operating leases (in thousands):

	For the Twelve Months Ended December 31,	
	2025	2024
Lease Cost:		
Amortization of finance ROU assets	$ 17	$ 771
Interest on finance lease liabilities	32	90
Operating lease cost	1,672	1,849
Variable lease cost	847	601
Total lease costs	2,568	3,311
Operating Sublease income	—	(385)
Total lease costs, net	$ 2,568	$ 2,926

During the year ended December 31, 2025, the Company disposed of research equipment classified as a ROU asset under a lease agreement. The ROU asset was sold, resulting in a loss of $43 thousand, which is included in the other expense line in the consolidated statements of operations and comprehensive loss for the period.

During the year ended December 31, 2024, the Company recognized impairment charges on certain finance right-of-use assets due to streamlining operations and focusing resources on advancing the clinical development of solnerstotug. These charges amounted to $0.6 million, which are not included in the regular amortization expense shown in the table above. The amount related to the right-of-use asset impairment is recorded in the long-lived asset impairment charges line in the consolidated statements of operations and comprehensive loss.

The following table contains a summary of other information pertaining to the Company's finance and operating leases (in thousands, except lease term and discount rate):

	For the Twelve Months Ended December 31,	
	2025	2024
Other Operating Lease Information:		
Operating cash outflows for operating leases	$ 1,748	$ 1,875
Operating cash inflows for operating subleases	$ —	$ (401)
Operating cash outflows for finance leases	$ 32	$ 90
Financing cash outflows from finance leases	$ 790	$ 811
Weighted average remaining lease term		
Operating leases	0.9 years	1.8 years
Financing leases	0.4 years	1.1 years
Weighted average discount rate		
Operating leases	7.6%	7.7%
Financing leases	9.4%	8.6%

The following table presents the maturity of the Company's operating and finance lease liabilities as of December 31, 2025 (in thousands):

	Operating	Financing
2026	$ 1,413	$ 81
2027	59	—
Total future minimum lease payments	1,472	81
Less amount representing interest	43	1
Total lease liabilities	$ 1,429	$ 80

License Agreements

In the normal course of business, the Company enters into licensing agreements with various parties to obtain the right to make, use, and sell licensed products currently in development.

Litigation

The Company records estimated losses from loss contingencies, such as a loss arising from a litigation, when it determines that it is probable a liability has been incurred and the amount of loss can be reasonably estimated. Litigation is subject to many factors that are difficult to predict so that there can be no assurance, in the event of a material unfavorable result in one or more claims, the Company will not incur material costs.

7. ACCOUNTS PAYABLE AND CURRENT ACCRUED LIABILITIES

Accounts payable and accrued liabilities consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Accounts payable	$ 689	$ 244
Accrued expenses	715	847
Accrued restructuring (Note 14)	—	31
Other current liabilities	77	126
Total	$ 1,481	$ 1,248

8. EQUITY

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends, unless declared by the board of directors.

Common Stock Warrants

There was no common stock warrant activity related to common stock warrants issued in conjunction with equity and debt fundraising events for the years ended December 31, 2025 and 2024. The following is a summary of the common stock warrants outstanding at December 31, 2025 and 2024:

	Number of Common Stock Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	20,609	$ 195.80	2.70	$ —
Expired	(19,466)	$ 79.00	—	—
Outstanding at December 31, 2025	1,143	$ 2,185.04	3.15	$ —

9. STOCK-BASED COMPENSATION

2018 Equity Incentive Plan

The Company's 2018 Stock Incentive Plan (the "2018 Plan"), provided for the Company to grant qualified incentive options, nonqualified options, stock grants and other stock-based awards to employees and non-employees to purchase the Company's common stock. Upon the effectiveness of the 2021 Plan, the Company ceased issuing new awards under the 2018 Plan.

2021 Equity Incentive Plan

The 2021 Plan became effective in February 2021. The 2021 Plan provides for the grant of incentive stock options to employees, including employees of any parent or subsidiary corporations, and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to employees, directors, and consultants, including employees and consultants of the Company's affiliates. The number of shares initially reserved for issuance under the 2021 Plan was 250,000 (5,000,000 prior to Reverse Stock Split), which began automatically increasing on January 1 of each calendar year, starting on January 1, 2022 through January 1, 2031, in an amount equal to 4.0% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the board of directors. As of December 31, 2025, 101,824 shares remained available for issuance pursuant to the 2021 Plan.

2021 Employee Stock Purchase Plan

The 2021 ESPP became effective in February 2021. A total of 16,666 shares (333,333 prior to Reverse Stock Split) of common stock were initially reserved for issuance under the 2021 ESPP, which will automatically increase on January 1 of each calendar year, beginning on January 1, 2022 through January 1, 2031, by an amount equal to 1.0% of the total shares of common stock outstanding on December 31st of the preceding calendar year. The purchase price of the shares under the 2021 ESPP are at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the purchase date. As of December 31, 2025, the Company had issued 12,220 shares under the 2021 ESPP, and 60,237 shares were available to be issued under the same plan.

Stock Options

The Company has granted options to purchase shares of common stock to employees and nonexecutive directors pursuant to the 2021 Plan at a weighted average fair value of $7.17 per share and $9.78 per share during the years ended December 31, 2025 and 2024, respectively. The Company uses the Black-Scholes option-pricing model to estimate the fair value of the stock options on the applicable grant dates.

The following is a summary of the stock option award activity during the year ended December 31, 2025:

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	264,741	$ 95.96	7.22	$ 41
Granted	47,224	$ 9.21		
Exercised	(395)	$ 6.40		
Forfeited	(11,105)	$ 13.02		
Expired	(28,221)	$ 133.22		
Outstanding at December 31, 2025	272,244	$ 80.56	6.98	$ 138
Vested or expected to vest as of December 31, 2025	272,244	$ 80.56	6.98	$ 138
Exercisable at December 31, 2025	203,451	$ 103.39	6.41	$ 87

The aggregate intrinsic value of the outstanding stock option awards is calculated as the difference between the exercise price and the market price of the Company's common stock at December 31, 2025. The aggregate intrinsic value of stock options exercised in the year ended December 31, 2025 was $1 thousand and there were no option exercises for the year ended December 31, 2024.

The total fair value of options vested during the years ended December 31, 2025 and 2024 was $1.3 million and $3.3 million, respectively.

At December 31, 2025, there was approximately $0.6 million of unrecognized stock-based compensation expense associated with the stock options, which is expected to be recognized over a weighted-average period of 2.26 years.

At December 31, 2024, there was approximately $1.5 million of unrecognized stock-based compensation expense associated with the stock options, which is expected to be recognized over a weighted-average period of 1.62 years.

Restricted Stock Units

The Company has granted restricted stock units with service-based vesting conditions.

The following is a summary of the restricted stock unit activity during the year ended December 31, 2025:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2024	4,178	$ 55.01
Vested	(1,768)	$ 61.07
Forfeited	(274)	$ 38.03
Unvested at December 31, 2025	2,136	$ 52.17

Pursuant to the 2021 Plan, the Company granted restricted stock units which vest annually over a period of one, two, three or four years.

At December 31, 2025, there was approximately $30 thousand of unrecognized stock-based compensation expense associated with the restricted stock units which is expected to be recognized over a weighted-average period of 0.81 years.

At December 31, 2024, there was approximately $0.1 million of unrecognized stock-based compensation expense associated with the restricted stock units which is expected to be recognized over a weighted-average period of 1.44 years.

Common Stock Warrants

The following is a summary of the common stock warrant activity during the years ended December 31, 2025:

	Number of Common Stock Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding and exercisable at December 31, 2024	229	$ 217.49	2.98	$ —
Outstanding and exercisable at December 31, 2025	229	$ 217.49	1.98	$ —

As of December 31, 2025, there was no unrecognized stock-based compensation expense associated with the common stock warrants.

During the years ended December 31, 2025 and 2024, the Company utilized the Black-Scholes option-pricing model for estimating the fair value of the stock options and common stock warrants granted. The following table presents the assumptions and the Company's methodology for developing each of the assumptions used:

	For the Year Ended December 31,	
	2025	2024
Volatility	94%-96%	91%-94%
Expected term (years)	5.5-6.0	4.9-6.0
Risk-free interest rate	4.2%-4.4%	3.8%–4.6%
Dividend rate	—%	—%

- Volatility—The Company lacks sufficient Company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies in addition to its own historical volatility and will continue to do so until it has adequate historical data regarding the volatility of its own traded stock price.
- Expected term—The Company calculates the expected term of options using the simplified method, as the Company lacks relevant historical data due to the Company's limited operating experience.
- Risk-free interest rate—The risk-free rate for periods within the estimated life of the stock award is based on the U.S. Treasury yield curve in effect at the time of grant.
- Dividend rate—The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future.

Stock-based compensation expense was recorded in the following line items in the consolidated statements of operations (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	$ 358	$ 846
General and administrative	916	2,289
Total stock-based compensation expense	$ 1,274	$ 3,135

10. EMPLOYEE RETIREMENT PLAN

The Company maintains a defined contribution 401(k) plan (the "Plan") for all employees. Under the Plan, participants may make voluntary contributions up to the maximum amount allowable by law. The Plan is based on employees' salary deferral, and the Company matches employees' contributions up to 4% of the employees' base salary. Employees are 100% vested in the Company's match contributions. During the years ended December 31, 2025 and 2024, the Company's matching contributions were $160 thousand and $238 thousand, respectively.

11. COMPENSATION AND EMPLOYEE BENEFITS

Compensation and employee benefits consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued incentive compensation	$ 111	$ 1,379
Accrued restructuring - compensation (Note 14)	1,159	445
Other compensation related liabilities	50	58
Total	$ 1,320	$ 1,882

12. INCOME TAXES

The components of net loss before income tax expense are as follows (in thousands):

	December 31, 2025	
	2025	2024
Domestic	$ (21,085)	$ (30,157)
Foreign	—	—
Total	$ (21,085)	$ (30,157)

Income tax expense consists of the following (in thousands):

	Year Ended December 31,	
	2025	2024
Current:		
Federal	$ —	$ —
State	—	—
Current tax provision	—	—
Deferred:		
Federal	(3,414)	(5,559)
State	795	(1,627)
Deferred tax benefit	(2,619)	(7,186)
Less change in valuation allowance	2,619	7,186
Total income tax provision	$ —	$ —

The components of the Company's loss before income tax expense is comprised solely of domestic sources. The effective income tax rate for the years ended December 31, 2025 and 2024 was different from the federal statutory income tax rate primarily due to the change in valuation allowance against deferred tax assets and permanent differences primarily related to equity based compensation. The reconciliation of the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31, 2025		Year Ended December 31, 2024	
	Amount	Percent	Amount	Percent
Pretax Loss	$ (21,085)		$ (30,157)	
US federal statutory tax rate	(4,428)	21%	(6,333)	21%
State and local income taxes, net of federal benefit	—	0.0%	—	0.0%
Change in valuation allowance	3,414	-16.2%	5,559	-18.4%
Nontaxable or nondeductible items:				
Equity-based compensation	399	-1.9%	343	-1.1%
Other	10	0.0%	42	-0.2%
Other adjustments:				
Net operating loss expiration	605	-2.9%	389	-1.3%
Total	$ -	0%	$ -	0%

The Company's effective tax rate differs from the statutory rate primarily due to continued losses and the maintenance of a full valuation allowance on deferred tax assets, resulting in zero income tax expense for the period.

Significant components of the Company's deferred tax assets and liabilities consist of the following (in thousands):

	December 31,	
	2025	2024
Net operating loss carryforwards	$ 42,095	$ 37,026
Equity-based compensation	3,353	3,815
Research and development tax credit carryforwards	1,364	1,364
Capitalized R&D expenditures	13,241	14,889
Lease liabilities	379	896
Other accruals	706	1,038
Total deferred tax assets	$ 61,138	$ 59,028
Valuation allowance	(60,796)	(58,180)
Net deferred tax assets	$ 342	$ 848
Deferred tax liabilities:		
Right-of-use assets	$ (342)	$ (848)
Total deferred tax liabilities	$ (342)	$ (848)
Net deferred tax assets (liability)	$ —	$ —

As of December 31, 2025, the Company has net operating loss carryforwards for federal and state tax reporting purposes of $170.5 million and $98.9 million, respectively, a portion of which expired beginning in 2025. Net operating loss carryforwards generated after December 31, 2017 for federal tax reporting purposes of $137.2 million have an indefinite life. The remaining federal net operating losses are subject to a 20-year carryforward period. As of December 31, 2025, the Company has research and development tax credit carryforwards of approximately $1.4 million, which expire beginning in 2034.

The utilization of NOLs and tax credit carryforwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that have occurred previously or may occur in the future. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, ("IRC"), a corporation that undergoes an ownership change may be subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes otherwise available to offset future taxable income and/or tax liability. An ownership change is defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three-year period. The Company has not completed a formal study to determine if any ownership changes within the meaning of IRC Section 382 and 383 have occurred as of December 31, 2025. An ownership change would restrict its ability to use its NOLs or tax credit carryforwards and could require the Company to pay federal or state income taxes earlier than would be required if such limitations were not in effect.

For tax years beginning after December 31, 2024, OBBBA ("One Big Beautiful Bill Act") enacted a new rule under Section 174A allowing companies to immediately expense any domestic research and developmental ("R&D") expenditures. For domestic R&D, companies may either immediately expense or elect to capitalize and amortize over at least 60 months under Section 174A. However, foreign R&D continues to require capitalization subject to the mandatory 15-year amortization period under Section 174.

The Company has elected to continue amortizing the previously capitalized costs over their remaining life. Beginning in tax year 2025, instead of immediately expensing domestic R&D expenditures under Section 174A, the Company elected to capitalize and amortize its domestic R&D expenditures under Section 59(e) over a 10 year period. Any foreign R&D costs will continue to be capitalized and amortized over 15 years in accordance with the requirements of Section 174.

A valuation allowance is required to be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. The Company has reviewed its positive and negative evidence and has concluded that it is more likely than not that the net deferred tax assets will not be realized; therefore, the Company continues to maintain a valuation allowance. The Company's valuation allowance increased by $2.6 million for the year ended December 31, 2025, primarily due to the generation of net operating losses.

The Company evaluates its uncertain tax positions under ASC 740-10, which requires that realization of an uncertain income tax position be recognized in the financial statements. The benefit to be recorded in the financial statements is the amount most likely to be realized assuming a review by tax authorities having all relevant information and applying current conventions. The Company concluded that there are no uncertain tax positions in any of the periods presented.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The earliest tax years that remain subject to examination by jurisdiction is 2022 for both federal and state. However, to the extent the Company utilizes net operating losses from years prior to 2022, the statute remains open to the extent of the net operating losses or other credits are utilized.

13. NET LOSS PER SHARE

Basic and diluted net loss per share attributable to common stockholders is calculated as follows (in thousands except share and per share amounts):

	For the Twelve Months Ended December 31,	
	2025	2024
Net loss	$ (21,085)	$ (30,157)
Net loss per share—basic and diluted	$ (16.72)	$ (24.01)
Weighted-average number of shares used in computing net loss per share—basic and diluted	1,260,772	1,255,776

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive:

	For the Year Ended December 31,	
	2025	2024
Stock options to purchase common stock	272,244	264,741
Unvested restricted stock units	2,136	4,178
Warrants issued to employees and contractor to purchase common stock	229	229
Warrants issued related to convertible notes and other equity agreements	1,143	20,609

14. RESTRUCTURING AND RELATED CHARGES

In November 2024, the Company announced a restructuring initiative to streamline operations and focus resources on advancing the clinical development of solnerstotug (the “2024 Restructuring”). As part of the 2024 Restructuring, the Company closed its research site in Rockville, Maryland, and reduced its workforce by approximately 46%, with the majority of reductions occurring in the preclinical research and development group. These actions were intended to extend the Company’s cash runway.

In October 2025, the Company announced it was exploring strategic alternatives. In November 2025, the Company’s Board of Directors approved a reduction in force of approximately 65% of the Company’s workforce (together with the October 2025 actions, the “2025 Restructuring”) to preserve capital while the Company evaluated potential mergers, asset sales, or other strategic transactions.

The 2024 Restructuring and 2025 Restructuring costs are primarily related to one-time termination benefits and ongoing benefit arrangements, both of which included severance payments and extended benefits coverage. Aggregate costs also included certain contract termination costs.

The following table summarizes the accrued liabilities activity recorded in connection with the 2024 Restructuring and 2025 Restructuring as of December 31, 2025 (in thousands):

	Personnel	Other	Total
Balance at January 1, 2024	$ —	$ —	$ —
Restructuring and other costs	723	31	754
Cash payments	(278)	—	(278)
Balance at December 31, 2024	445	31	476
Restructuring and other costs, net	25	(2)	23
Cash payments	(346)	(16)	(362)
Balance at March 31, 2025	124	13	137
Restructuring and other costs, net	—	(3)	(3)
Cash payments	(124)	(6)	(130)
Balance at June 30, 2025	—	4	4
Restructuring and other costs, net	—	(4)	(4)
Cash payments	—	—	—
Balance at September 30, 2025	—	—	—
Restructuring and other costs, net	1,671	—	1,671
Cash payments	(512)	—	(512)
Balance at December 31, 2025	$ 1,159	$ —	$ 1,159

15. SUBSEQUENT EVENTS

Merger Agreement and Private Placement

On February 17, 2026, the Company acquired Faeth Holdings Therapeutics, Inc. ("Faeth HoldCo") and its wholly owned subsidiary Faeth Therapeutics, LLC ("Faeth Subsidiary" and, together with Faeth HoldCo, “Faeth Therapeutics”) pursuant to an Agreement and Plan of Merger (the “Merger Agreement”), dated as of February 17, 2026, by and among the Company, its merger subsidiaries, Faeth HoldCo and Faeth Subsidiary. The acquisition was structured as a stock-for-stock transaction pursuant to which all of Faeth HoldCo's outstanding shares of capital stock were exchanged based on a fixed exchange ratio for 10,497.0980 shares of Series B Non-Voting Convertible Preferred Stock (representing 10,497,098 shares on an as-converted-to-common basis and without giving effect to any beneficial ownership limitations), (ii) the outstanding warrant to purchase shares of Faeth Subsidiary capital stock was converted into a warrant to purchase an aggregate of 2.1020 shares of Series B Non-Voting Preferred Stock (representing a warrant to purchase 2,102 shares of Common Stock on an as-converted-to-common basis and without giving effect to any beneficial ownership limitations) and (iii) all outstanding options to purchase Faeth Subsidiary common stock were assumed by the Company and converted into options to purchase an aggregate of 252,210 shares of Common Stock. While the Company continues to evaluate the accounting for the transaction, the Company currently expects to account for it as an asset acquisition.

Concurrently with the acquisition of Faeth Therapeutics, the Company entered into a definitive agreement for a private placement financing with new and returning investors to raise $200 million of gross proceeds in which the investors were issued an aggregate of 14,440.395 shares of Series B Non-Voting Convertible Preferred Stock (or 14,440,395 on an as-converted-to-common basis and without giving effect to any beneficial ownership limitations) at a price of approximately $13,850 per share (or approximately $13.85 per share on an as-converted-to-common basis). The private placement financing closed on February 20, 2026.

Subject to the receipt of stockholder approval of the Parent Stockholder Matters (as defined in the Merger Agreement), each share of Series B Non-Voting Convertible Preferred Stock will automatically convert into 1,000 shares of Common Stock, subject to certain beneficial ownership limitations established by each holder. As a result of the transactions, equityholders of the Company immediately prior to the acquisition owned approximately 4.9% of the Common Stock, equityholders of Faeth Therapeutics immediately prior to the acquisition owned approximately 40.6% of the Common Stock and investors in the private placement financing owned approximately 54.5% of the Common Stock, in each case, calculated on a fully-diluted, as-converted-to-common basis (and without giving effect to any beneficial ownership limitations) using the treasury stock method and based on the implied equity values of the Company and Faeth Therapeutics.