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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A
(Amendment No. 1)

(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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Explanatory Note

Sensei Biotherapeutics, Inc. (the "Company") is filing this Amendment No. 1 on Form 10-K/A ("Amendment No. 1") to amend the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025, which was originally filed with the U.S. Securities and Exchange Commission (the "SEC") on March 30, 2026 (the "Original Filing"). The purpose of this Amendment No. 1 is to amend and replace in its entirety Part I, Item 1. Business of the Original Filing in response to comments received from the staff of the SEC.

In addition, pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended, this Amendment No. 1 contains revised certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, which are attached hereto as Exhibits 31.3 and 31.4. Because no financial statements or other financial information have been included in this Amendment No. 1, paragraph 3 has been omitted from each of the revised Section 302 Certifications, and because this Amendment No. 1 does not contain or amend any disclosure with respect to Items 307 and 308 of Regulation S-K, paragraphs 4 and 5 have been omitted from each of the revised Section 302 certifications.

Except as described above, this Amendment No. 1 does not amend, modify, or otherwise update any other information in the Original Filing and does not reflect events occurring after the filing of the Original Filing. Accordingly, this Amendment No. 1 should be read in conjunction with the Original Filing and the Company's other filings with the SEC.

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.

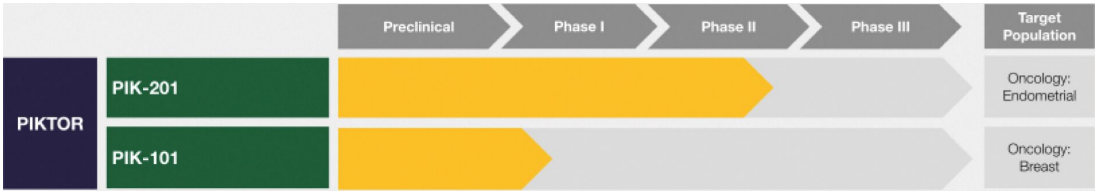
Following the Acquisition, our lead program is PIKTOR, an investigational multi-node inhibitor, or MNI, of the PI3K/AKT/mTOR pathway in development for endometrial and breast cancer. The PI3K/AKT/mTOR pathway is dysregulated in up to 50% of all solid tumors, making it one of the most prevalent therapeutic 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. The primary endpoint for this Phase 2 trial is objective response rate (ORR), and the secondary endpoints are progression free survival (PFS), PFS at six months, overall survival, clinical benefit rate (CBR), duration of response (DOR) and safety and tolerability by assessment of adverse events (AEs) and serious adverse events (SAEs). In May 2026, we announced that we had dosed the first patient in our Phase 1b trial in HR+/HER2- advanced breast cancer (Study FTH-PIK-101). The primary endpoint for this Phase 1b trial is safety and tolerability by assessment of AEs and SAEs, and the secondary endpoints are ORR, PFS, PFS at six months, overall survival, CBR and DOR.

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:

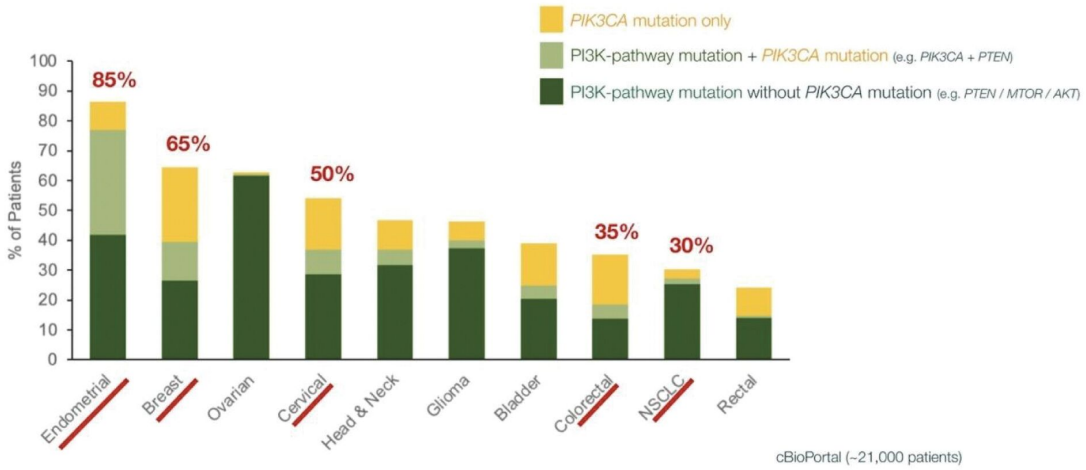
- We intend to establish PIKTOR's initial therapeutic proof of concept in endometrial cancer through our ongoing Phase 2 trial (FTH-PIK-201), with topline data anticipated by year-end 2026 and longer-term follow-up data in 2027.
- Concurrently, we plan to broaden PIKTOR's development into advanced HR+/HER2- breast cancer through Study FTH-PIK-101, for which we announced in May 2026 that the first patient was dosed, and expect 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.

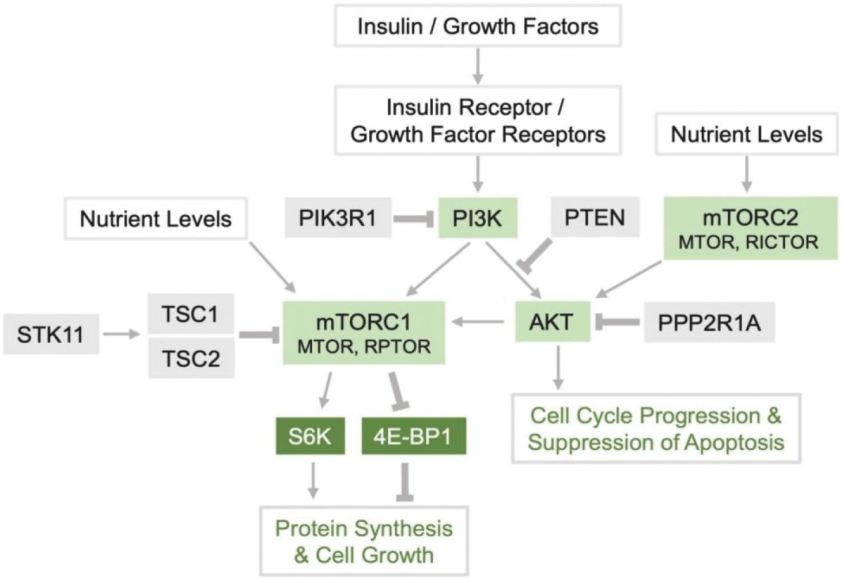
The key components of the pathway are:

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.

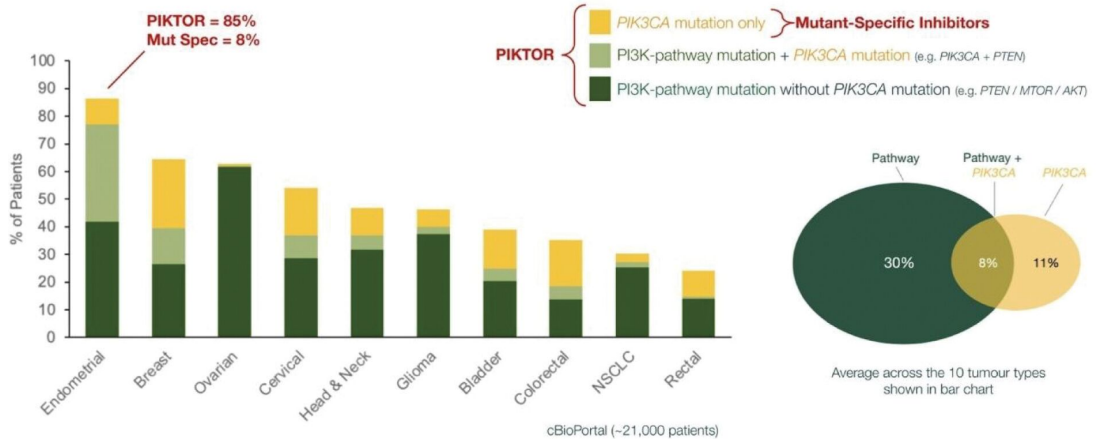
Mechanistic target of rapamycin (mTOR), which orchestrates cell growth, proliferation and survival by determining whether cells grow and divide or conserve their resources in response to signals from PI3K/AKT. mTOR operates through two distinct complexes: mTORC1 and mTORC2. mTORC1 is activated when nutrients 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.

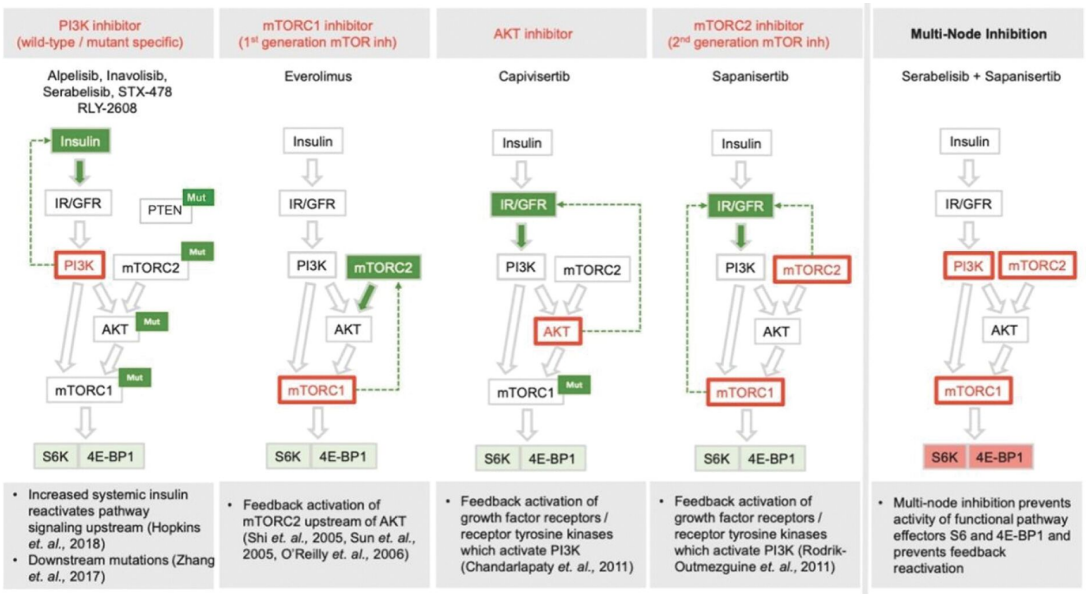
PIKTOR—Our Lead Clinical Candidate

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

- **Potentially compelling emerging tolerability profile**, with rates of hyperglycemia and stomatitis observed in our Phase 2 clinical trial of PIKTOR in advanced endometrial cancer (Study FTH-PIK-201) as of the January 2026 data cutoff of 13.6% any grade and 4.5% grade 3/4 (hyperglycemia) and 13.6% any grade, 0% grade 3/4 (stomatitis), as described in the "Emerging Safety Profile" section below
- **Potentially differentiated potency,** with preclinical data demonstrating that PIKTOR deeply inhibited signaling across multiple nodes of the PI3K/AKT/mTOR pathway
- **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

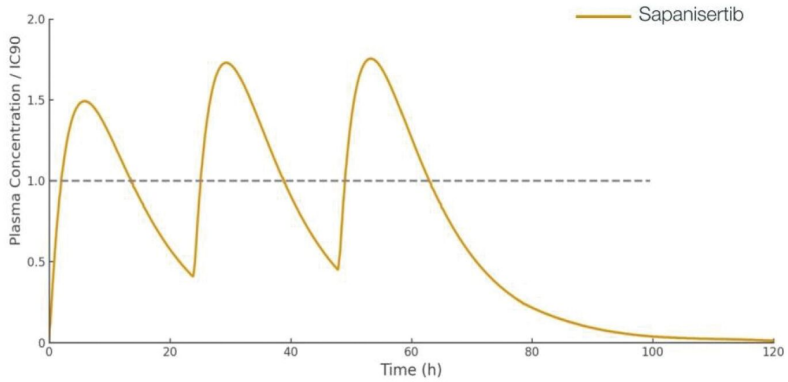
In a head-to-head preclinical study, PIKTOR achieved pathway suppression at lower concentrations than other PI3K/AKT/mTOR targeted agents

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 of a preclinical head-to-head comparison of PIKTOR to Gedatolisib. 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 consistent experimental conditions and protocols. Drug concentrations for each agent were selected to cover the full range of inhibitory concentrations (0% inhibition to 100% inhibition) so that IC50 for each agent could be calculated. 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

We believe clinical data to date suggest a potentially compelling tolerability profile. 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. In our Phase 2 clinical trial of PIKTOR in advanced endometrial cancer (Study FTH-PIK-201), as of our January 2026 data cutoff, we have observed that out of 22 patients, patients experienced stomatitis (13.6% any grade, 0% grade 3/4) and hyperglycemia (13.6% any grade and 4.5% grade 3/4).

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 serious adverse events, or SAEs, all non-fatal, were reported across the three trials. By type, these were increased transaminases (2), fatigue (2), nausea (2), vomiting (2), and enterocolitis, general physical health deterioration, hyperglycemia, pyrexia, and septic shock (one each).

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. Study X31025 was conducted by Dr. David Starks and Dr. Casey Williams at Avera Cancer Institute in Sioux Falls, South Dakota from July 2017 to July 2020. The primary endpoints were safety and tolerability, the determination of a maximum tolerated dose of PIKTOR in combination with weekly paclitaxel and to recommend a Phase 2 dose of PIKTOR in combination with weekly paclitaxel, the secondary endpoint was ORR and the exploratory endpoints were to describe Health Related Quality of Life outcomes as measured by the Treatment Related Symptom Checklist and HRQOL-LASA and biomarker assessment. This trial was not powered for statistical significance as it was a Phase 1b dose escalation study evaluating safety as the primary endpoint. The data from Study X31025, which we summarize below, was reported in *Gynecologic Oncology* in 2022.

Efficacy Results

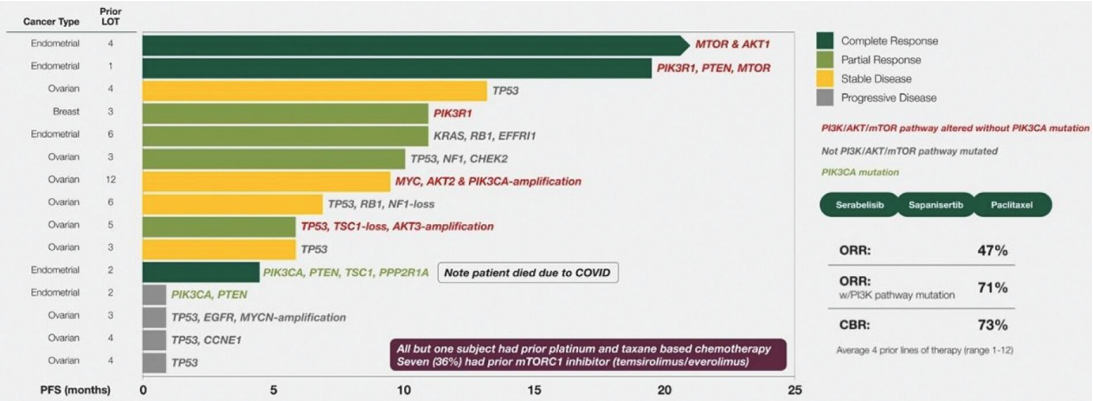
At the conclusion of the study, 15 patients were evaluable for efficacy. The remaining four patients in the trial were not evaluable for efficacy because they did not complete the first cycle of the trial and therefore per protocol were not included in calculating ORR, CBR or any other measures. For the evaluable patients, the ORR was 47% and the CBR was 73%. 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

Amongst the seven response-evaluable patients expressing at least one PI3K/AKT/mTOR pathway mutation, the ORR increased to 71%.

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 (4mg of sapanisertib, 200mg of serabelisib and 80 mg/m^2 of paclitaxel), was observed (renal failure secondary to hyperglycemia). The most frequent grade 3 or 4 adverse events were decreased white blood cells, nonfebrile neutropenia, hypophosphatemia, hyperglycemia, anemia, and elevated liver enzymes. The publication did not separately report SAEs.

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 the ongoing Study FTH-PIK-201. The dosing level in this trial is 3 mg sapanisertib, 200 mg serabelisib, 80 mg/m^2 paclitaxel. 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) . Of note, patients in the PIK-201 study are not required to use any steroid mouthwash prophylaxis. The SAEs, regardless of attribution, that were observed in the trial as of the January 2026 data snapshot were sepsis (2), increased alanine aminotransferase (1), increased aspartate aminotransferase (1), embolism (1), flank pain (1), hyperglycemia (1), pneumonia (1), pyelonephritis (1), toxicity to various agents (1), tracheal hemorrhage (1), urosepsis (1), and UTI (1); of note, only the increased alanine aminotransferase and hyperglycemia were determined by the investigator to be related to study treatment.

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.

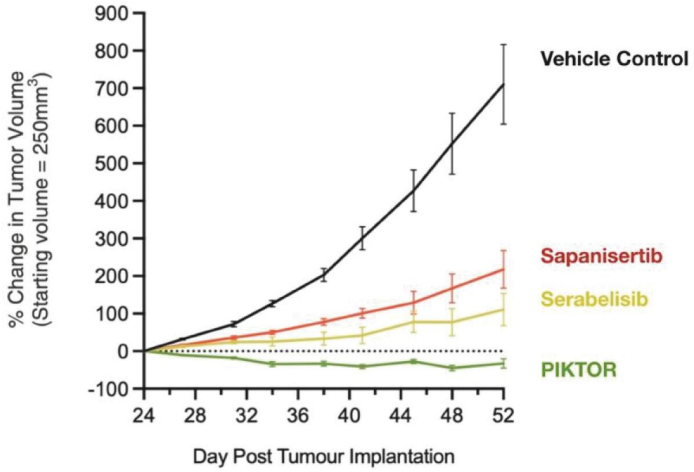
MNI Class Validation via Gedatolisib

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.

In the Phase 3 VIKTORIA-1 trial (PIK3CA wild-type cohort), gedatolisib demonstrated 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 2.0 months for fulvestrant alone. We believe these results support the rationale for multi-node inhibition of the PI3K/AKT/mTOR pathway.

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) showed 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, demonstrated antitumor activity (21.3% ORR; 7.2 months median PFS) in advanced HR+/HER2- breast cancer patients.

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

Study FTH-PIK-101

Study FTH-PIK-101 is our Phase 1b open-label, dose escalation trial of PIKTOR in advanced HR+/HER2- breast cancer, for which we announced that we had dosed the first patient in May 2026. 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. The primary endpoint for this Phase 1b trial is safety and tolerability by assessment of AEs and SAEs, and the secondary endpoints are ORR, PFS, PFS at six months, overall survival, CBR and DOR.

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 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%.

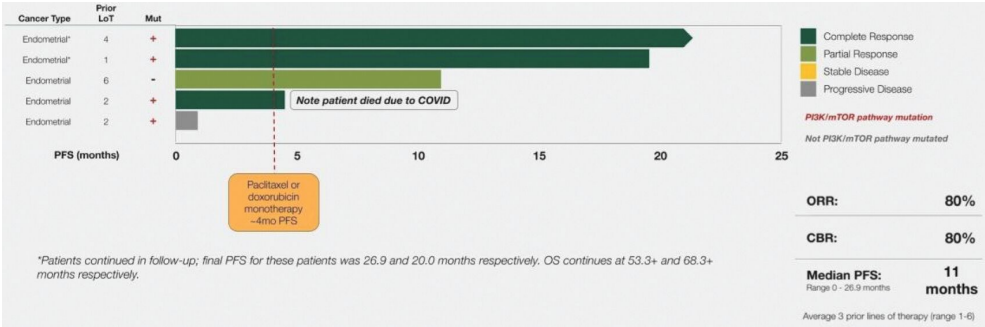
At least one PI3K/AKT/mTOR pathway mutation is present in approximately 80% of endometrial tumors, however, there are currently no approved PI3K/AKT/mTOR pathway inhibitors for endometrial cancer.

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.

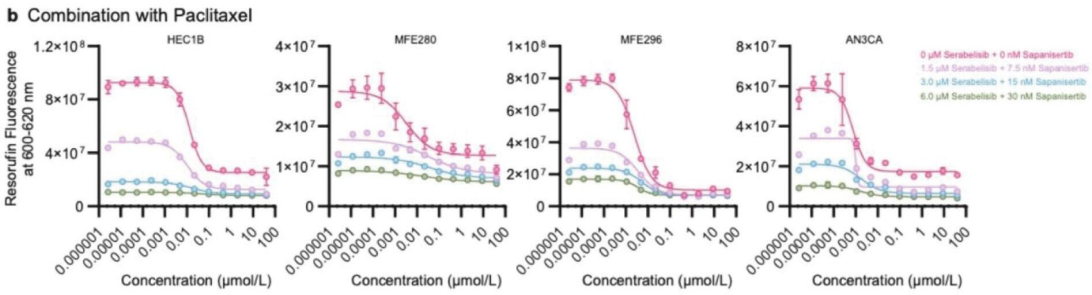
PIKTOR's Development Rationale

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. 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 the following secondary endpoints: PFS, PFS at six months, overall survival, CBR, DOR and safety and tolerability by assessment of AEs and SAEs. The trial protocol does not establish a specific target ORR for the primary endpoint; ORR will be evaluated against the historical benchmark for single-agent chemotherapy in this setting, consistent with the design of single-arm, open-label Phase 2 trials. 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 intend to evaluate the results of this trial in 2026 to determine next steps. 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, which we are evaluating for potential development.

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 including pharmaceutical formulation CMC development efforts, 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 (e.g., including patents covering serabelisib and sapanisertib as compounds per se and pharmaceutical formulations), 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.

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 (previously filed as Exhibit 4.1 to the Form 10-K).
4.2‡	Warrant to Purchase Stock, dated as of September 7, 2021, by and between Faeth Therapeutics, Inc. and Western Alliance Bank (previously filed as Exhibit 4.2 to the Form 10-K).
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 (previously filed as Exhibit 10.6 to the Form 10-K).

Exhibit Number	Description
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 (previously filed as Exhibit 10.10 to the Form 10-K).
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 (previously filed as Exhibit 10.14 to the Form 10-K).
10.15	Amended Retention Agreement, dated as of February 17, 2025, entered into with Josiah Craver (previously filed as Exhibit 10.15 to the Form 10-K).
10.16	Open Market Sales Agreement℠, 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 (previously filed as Exhibit 10.19 to the Form 10-K).
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 (previously filed as Exhibit 10.20 to the Form 10-K).

Exhibit Number	Description
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. (previously filed as Exhibit 10.21 to the Form 10-K).
10.22†	Letter Agreement, dated as of May 15, 2023, between Millennium Pharmaceuticals, Inc. and Faeth Therapeutics, Inc. (previously filed as Exhibit 10.22 to the Form 10-K).
10.23†	Letter Agreement dated as of January 29, 2026, between Millennium Pharmaceuticals, Inc., Takeda Pharmaceutical Company Limited and Faeth Therapeutics, Inc. (previously filed as Exhibit 10.23 to the Form 10-K).
10.24	Retention Agreement, dated as of December 22, 2025, entered into with Christopher Gerry (previously filed as Exhibit 10.24 to the Form 10-K).
10.25	Retention Agreement, dated as of December 22, 2025, entered into with Josiah Craver (previously filed as Exhibit 10.25 to the Form 10-K).
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 (previously filed as Exhibit 21.1 to the Form 10-K).
23.1	Consent of Deloitte & Touche LLP, independent registered public accounting firm (previously filed as Exhibit 23.1 to the Form 10-K).
24.1	Power of Attorney (previously filed within the signature page of the Form 10-K).
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 (previously filed as Exhibit 31.1 to the Form 10-K).
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 (previously filed as Exhibit 31.2 to the Form 10-K).
31.3*	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.
31.4*	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 (previously filed as Exhibit 32.1 to the Form 10-K).
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 Amendment No. 1 to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Sensei Biotherapeutics, Inc.

Date: June 2, 2026

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

Exhibit 31.3

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Christopher W. Gerry, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2025 of Sensei Biotherapeutics, Inc. (the "registrant"); and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: June 2, 2026

By: /s/ Christopher W. Gerry
Christopher W. Gerry
President and General Counsel
(Principal Executive Officer)

Exhibit 31.4

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Josiah Craver, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2025 of Sensei Biotherapeutics, Inc. (the "registrant"); and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: June 2, 2026

By: /s/ Josiah Craver
Josiah Craver
Senior Vice President, Finance
(Principal Financial Officer)