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

FORM 10-K

☒ **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: 001-41929

ARRIVENT BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**86-3336099**
(State of Other Jurisdiction of incorporation or Organization)	(I.R.S. Employer Identification No.)
18 Campus Boulevard Suite 100, Newtown Square, PA	**19073**
(Address of principal executive offices)	(Zip Code)

(628) 277-4836

(Registrant's telephone number, including area code)

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	**AVBP**	**Nasdaq Global Market**

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 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 (§232.0405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of the shares of common stock on The Nasdaq Global Market on June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter), was $762,664,165.

The number of shares of registrant's common stock outstanding as of March 4, 2026 was 44,201,622.

Documents Incorporated by Reference

The information required by Part III of this Annual Report on Form 10-K, to the extent not set forth herein, is incorporated herein by reference from the registrant's definitive proxy statement relating to the Annual Meeting of Stockholders to be held in 2026, which definitive proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (Annual Report) contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, plans for our product candidates, planned preclinical studies and clinical trials, results of clinical trials, future research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the timing, progress and results of preclinical studies and clinical trials for our product candidates, including our product development plans and strategies;
- estimates of our addressable market, market growth, future revenue, key performance indicators, expenses, capital requirements and our needs for additional financing;
- our ability to obtain funding for our operations;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- the timing or likelihood of regulatory filing and approvals;
- the commercialization of our product candidates, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;
- our ability to source sufficient clinical product for our clinical trials and, if our product candidates are approved and commercialized, commercial product;
- the impact of tariffs and changes in economic policies, volatility in inflation, volatility in interest rates, or market disruptions on our business; and
- our financial performance.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject and are based on information available to us as of the date of this Annual Report. Although we believe such information forms a reasonable basis for the expectations reflected in the forward-looking statements, such information may be limited or incomplete, and we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed with the Securities and Exchange Commission (SEC) as exhibits to this Annual Report with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

This Annual Report includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the markets in which we operate and intend to operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates.

This Annual Report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company dedicated to the identification, development and commercialization of differentiated medicines to address the unmet medical needs of patients with cancers. We seek to utilize our team's deep drug development experience to maximize the potential of our lead product candidate, firmonertinib, and advance a pipeline of novel therapeutics, such as next-generation antibody drug conjugates, including ARR-217 (MRG007), through approval and commercialization in patients suffering from cancer, with an initial focus on solid tumors. Firmonertinib is currently being evaluated in multiple clinical trials across a range of epidermal growth factor receptor (EGFR) mutations (EGFRm) in non-small cell lung cancer (NSCLC). We are conducting a pivotal Phase 3 clinical trial of firmonertinib in treatment naive, or first-line, patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations and a pivotal Phase 3 clinical trial of firmonertinib in first-line patients with locally advanced or metastatic EGFRm NSCLC with P-loop and-alpha-c-helix compressing (PACC) mutations. We are conducting a Phase 1 clinical trial of ARR-217 in patients with unresectable locally advanced or metastatic solid tumors.

We received Breakthrough Therapy Designation (BTD) for firmonertinib for first line EGFRm NSCLC with exon 20 insertion from the U.S. Food and Drug Administration (FDA) in October 2023, and Orphan Drug Designation for treatment of NSCLC with EGFRm or human epidermal growth factor receptor 2 (HER2) mutations or human epidermal growth factor receptor 4 (HER4) mutations in February 2024. A product candidate can receive BTD if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have received BTD, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development, although BTD may not result in a faster development process, review or approval and does not increase the likelihood that the product candidate will ultimately receive FDA approval for any indication.

In 2021, we licensed from Shanghai Allist Pharmaceuticals, Co. Ltd (Allist) the right to develop and commercialize firmonertinib worldwide, with the exception of greater China, which includes mainland China, Hong Kong, Macau and Taiwan. Firmonertinib is an investigational, novel, EGFR mutant-selective tyrosine kinase inhibitor (TKI) that we are developing for the treatment of NSCLC patients across a broader set of EGFR mutations (EGFRm) than are currently served by approved EGFR TKIs. Firmonertinib is currently only approved and commercially distributed by Allist in China as a first-line therapy to treat classical EGFRm NSCLC. The FDA has not approved firmonertinib for any use. We selected firmonertinib for global development against nonclassical, or uncommon, mutations based on preliminary reductions in tumor size observed in seven out of ten patients with EGFR exon 20 insertion mutations treated with firmonertinib in the ongoing Phase 1b clinical trial, the FAVOUR trial, conducted by Allist in China, and preclinical activity in PACC mutations, each a subtype of uncommon mutation. In a subsequent interim data readout from the FAVOUR trial of firmonertinib administered at 240 mg once daily in first-line patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations, 79% of patients (n=22 out of 28 patients) were observed to experience a reduction in tumor size of at least 30%. In a final analysis from the Phase 1b FURTHER trial of firmonertinib, which included a cohort of EGFRm NSCLC with PACC mutations, we observed 16.0 months median progression free survival (mPFS) with firmonertinib 240 mg in first-line, confirmed overall response rate (cORR) 68.2% (n=15 out of 22 1L patients at 240mg) and duration of response (DOR) 14.6 months, and confirmed CNS (central nervous system) responses with firmonertinib including complete responses (CRs).

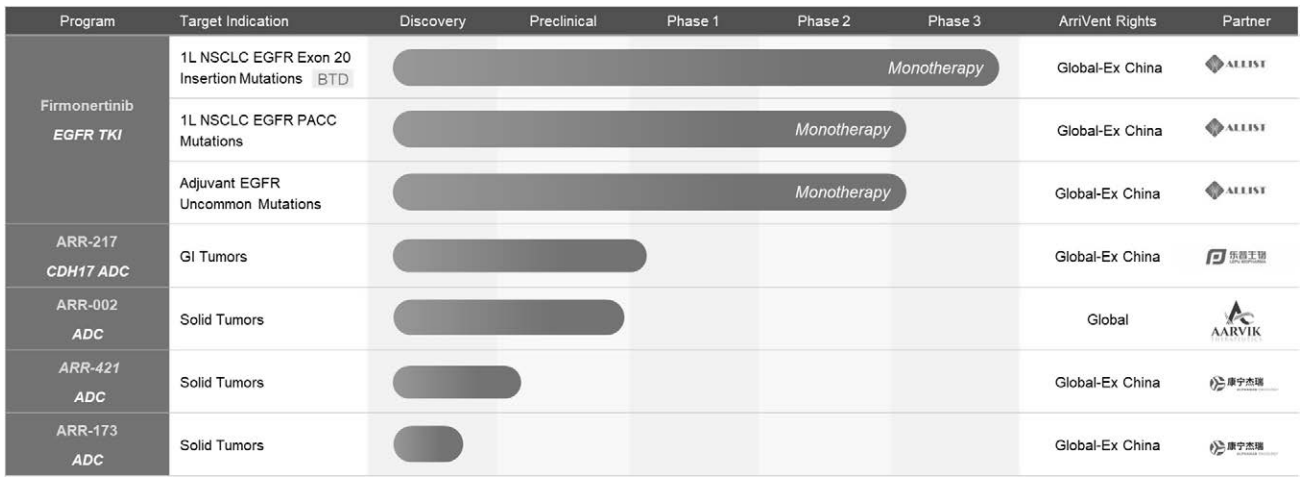
As one of the most prevalent cancers in the world, lung cancer imposes a significant global burden on human health, and EGFRm NSCLC represents a significant proportion of those affected. Despite progress in the therapeutic landscape for EGFRm NSCLC, many patients, particularly those with uncommon mutations, such as exon 20 insertions or PACC mutations, are underserved by existing treatments. In an interim data readout from the FAVOUR trial of firmonertinib administered at 240 mg once daily in first-line patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations, 79% of patients (n=22 out of 28 patients) were observed to experience a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression as measured by Response Evaluation

Criteria in Solid Tumors (RECIST) 1.1 criteria. This measurement of reduction is the threshold in this trial for a partial response and for inclusion in determination of the overall response rate (ORR), which is the primary endpoint of this trial. In the same interim data readout, those 79% of patients were observed to experience a 15.2 month median DOR. Interim results may not be indicative of final results; however, we believe these interim clinical results underscore firmonertinib's potential in patients whose tumors contain an uncommon EGFRm.

We are currently conducting a pivotal Phase 3 clinical trial, the FURVENT clinical trial, in first-line locally advanced or metastatic non-squamous EGFRm NSCLC patients with exon 20 insertion mutations and we expect topline data from this trial in mid-2026. Additionally, we are conducting a pivotal Phase 3 clinical trial, the ALPACCA clinical trial, in first-line locally advanced or metastatic non-squamous EGFRm NSCLC patients PACC mutations. In September 2025, our final Phase 1b PACC data reported 68.2% of patients (n=15 out of 22 1L patients at 240 mg) were observed to experience a confirmed reduction in tumor size of at least 30% from the baseline without evidence of progression as measured by RECIST 1.1 criteria. The confirmed mPFS in these patients was 16.0 months.

Since our inception in 2021, we have assembled a robust oncology pipeline by leveraging our global network and our experience in business development transactions. In 2021, we licensed from Allist the right to develop and commercialize firmonertinib worldwide, with the exception of greater China, which includes mainland China, Hong Kong, Macau and Taiwan. Also in 2021, we entered into a research collaboration, as amended, with Aarvik Therapeutics, Inc. (Aarvik) to leverage its proprietary multi-target, multivalent, site-specific conjugation antibody platform to discover next-generation antibody drug conjugates (ADCs) with improved activity and safety over single target bivalent ADCs. In 2024, we entered into a collaboration agreement with Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab), a wholly owned subsidiary of Alphamab Oncology, to discover, develop and commercialize novel ADCs for the treatment of cancers globally, with the exception of greater China, which includes mainland China, Hong Kong, Macau and Taiwan. In January 2025, we entered into an Exclusive License Agreement (the Lepu Biopharma Agreement) with Lepu Biopharma Co. Ltd. (Lepu Biopharma) pursuant to which Lepu Biopharma granted us the right to develop and commercialize ARR-217 (MRG007), a CD-H17-targeting ADC for gastrointestinal cancers outside greater China, which includes mainland China, Hong Kong, Macau, and Taiwan.

We plan to continue to engage in business development activities to source additional innovative therapeutics in areas currently underserved by approved therapies. This broader strategy includes evaluating research collaborations, partnerships and licensing arrangements intended to expand our development pipeline of differentiated and next-generation oncology assets. The following table summarizes our current pipeline indicating the most advanced stage of development:



NSCLC: non-small cell lung cancer; EGFR: epidermal growth factor receptor; PACC: P-loop alpha-c helix compressing; TKI: tyrosine kinase inhibitor; BTD: Breakthrough Therapy Designation; ADC: Antibody Drug Conjugate; GI Tumors: gastrointestinal tumors; 1L: First-line therapy; Global Ex-China: Worldwide, except mainland China, Hong Kong, Macau and Taiwan.

Currently approved EGFR TKIs have achieved considerable commercial success and have become the standard of care for patients with NSCLC with classical EGFRm which comprise approximately 69% of all EGFRm NSCLC patients. However, many of these therapies, including AstraZeneca plc's (AstraZeneca) third-generation EGFR TKI, osimertinib (TAGRISSO®), are minimally active against or not approved for use in a significant portion of NSCLC patients with uncommon EGFRm. This unmet need leaves many EGFRm NSCLC patients with few effective treatment options. Firmonertinib is currently approved and commercially distributed by Allist in China as a first-line therapy to treat classical EGFRm NSCLC. However, firmonertinib was designed to have strong inhibitory activity, not only against classical EGFRm, but also against uncommon EGFRm, such as exon 20 insertion and PACC mutations which together account for approximately 22% of EGFRm NSCLC.

To date, firmonertinib has been evaluated in multiple clinical trials with an aggregate patient population of over 1,000 patients against a broad range of EGFRm NSCLC, including both classical and uncommon EGFRm. Based on the results of preclinical and clinical trials conducted to date, we believe that firmonertinib has the potential to retain many of the key advantages of third-generation EGFR TKIs compared to first- and second-generation EGFR TKIs, including overcoming T790M mutations that confer resistance to earlier generation TKIs, while also targeting a broader set of EGFRm. In 2022, Allist reported the results of its FURLONG clinical trial, a double blind, placebo-controlled Phase 3 clinical trial of firmonertinib in first-line NSCLC patients with classical EGFRm. In FURLONG, firmonertinib was compared with the first-generation EGFR TKI, gefitinib, and demonstrated superior progression free survival (PFS) over gefitinib, showing a median PFS of 20.8 months versus 11.1 months for gefitinib. Firmonertinib's ability to cross the blood-brain barrier was also demonstrated in this clinical trial with a central nervous system (CNS) metastases specific ORR, which measured reduction of tumor size of at least 30% in brain metastases if present at the start of therapy, of 91% versus 65% for gefitinib. Based on observed clinical activity against exon 20 insertions in the FAVOUR clinical trial and observed activity against PACC mutations in the FURTHER clinical trial, we believe firmonertinib is potentially differentiated from third-generation EGFR TKIs approved for classical EGFRm NSCLC.

In the United States and the European Union, standard of care for first-line therapy in EGFRm NSCLC involving exon 20 insertion mutations is platinum-based chemotherapy with pemetrexed with or without amivantamab. These regimens have significantly lower response rates and DOR compared to results achieved in first-line patients with classical EGFRm who can be treated with approved third-generation EGFR TKIs. Over 9% of EGFRm NSCLC patients are estimated to have exon 20 insertion mutations. However, amivantamab appears to lack brain penetrance to effectively treat brain metastasis. In March 2024 and July 2024, amivantamab in combination with chemotherapy, was approved in the United States and Europe, respectively, for first line EGFRm NSCLC patients with exon 20 insertion mutations. However, amivantamab is an intravenously administered biologic lacking the advantages of oral therapies. Furthermore, amivantamab is being dosed in combination with chemotherapy in this setting with chemotherapy associated toxicities. We believe firmonertinib, if approved, has the potential to become a chemotherapy-free oral regimen in first-line EGFRm NSCLC patients with exon 20 insertion mutations given the clinical data generated in this patient population to date.

Guidelines employing TKIs for the treatment of many of the PACC EGFRm are not established and, as a result, chemotherapy is often used as the default course of therapy, offering limited efficacy and introducing chemotherapy-related toxicity. Afatinib (GILOTRIF®), a second-generation TKI, is also used in some patients, but has an unfavorable safety profile and is not brain penetrant. Osimertinib is frequently used in some patients, but the activity of osimertinib in such patients is less than its activity in patients with classical EGFRm NSCLC. Over 12% of EGFRm NSCLC patients are estimated to have PACC mutations. If approved, we believe firmonertinib has the potential to become a leading treatment option for first-line EGFRm NSCLC patients with PACC mutations based on firmonertinib's preclinical and clinical activity observed against these mutations and the evaluation of firmonertinib in multiple clinical trials.

Our Firmonertinib Development Initiative

We have designed a robust global clinical development plan across a broad spectrum of EGFRm NSCLC patient populations for which we believe firmonertinib will have a differentiated profile compared to currently available treatments. The following table describes the key planned and ongoing clinical trials of firmonertinib conducted by us or our collaboration partners:

						EGFRm Patient Population							
						Exon 20			PACC			Classical	
Trial	Phase	Trial Rationale	Status	Next Anticipated Milestone	Geography	Adj	1L	2L+	Adj	1L	2L+	1L	2L+
FURVENT	*Phase 3*	Pivotal trial for Exon 20	Completed Enrollment	Topline data in early 2026	Global		✓						
FAVOUR	*Phase 1b*	Proof of Concept (PoC) in Exon 20	Completed Enrollment	Publication in 2026	China*		✓	✓					
ALPACCA	*Phase 3*	Pivotal Trial for PACC	Enrolling		Global					✓			
Adjuvant*	*Phase 3*	Pivotal trial for Uncommon Mutations	Planned	-	Global	✓			✓				
FURLONG	*Phase 3*	Pivotal trial for Classical	Completed Study	-	China*							✓	

* Allist sponsor; 1L: First-Line Therapy; 2L+: Second-line or greater therapy.

FURVENT — Our Ongoing Phase 3 Clinical Trial in First-Line Non-Squamous Locally Advanced or Metastatic EGFRm NSCLC Patients with Exon 20 Insertion Mutations

We enrolled 398 patients in FURVENT, a global, pivotal Phase 3 clinical trial of firmonertinib in first-line non-squamous locally advanced or metastatic NSCLC patients with exon 20 insertion mutations being conducted jointly with Allist. Our FURVENT clinical trial is designed to assess the safety and efficacy of firmonertinib administered at either 160 mg or 240 mg, once-daily as compared to platinum-based chemotherapy with pemetrexed, the current first-line standard of care. The primary endpoint of this study is PFS. We enrolled 398 patients globally, including from sites in the United States, Europe and certain Asian countries including China. We expect topline data from our FURVENT clinical trial in mid-2026.

FAVOUR — Phase 1b Clinical Trial in NSCLC Patients with EGFR Exon 20 Insertion Mutations

The FAVOUR clinical trial is an ongoing 90-patient Phase 1b clinical trial being conducted by Allist in China that is intended to assess the safety and efficacy of firmonertinib in locally advanced or metastatic NSCLC patients who have EGFR exon 20 insertion mutations. First-line patients receive 240 mg firmonertinib once daily. Patients that have received prior treatment are randomized to receive either 160 mg or 240 mg of firmonertinib once daily. Initial data obtained through June 15, 2023 showed a confirmed ORR (defined as a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression), among patients evaluable as of that date of 79% among the treatment-naïve patients cohort, 46% among the pretreated 240 mg cohort and 39% in the pretreated 160 mg cohort. Median DOR was 15.2 months in treatment-naïve patients, 13.1 months in the 240 mg pretreated cohort and 9.7 months in the 160 mg pretreated cohort. Firmonertinib was observed to be generally well tolerated in all clinical trial cohorts to date with a low rate of discontinuation due to treatment-related adverse events (TRAEs). As of June 15, 2023, treatment related serious adverse events (TRSAEs) were observed in 6 out of 86 of the treated patients and 2 out of 86 patients discontinued participation in the trial as a result of TRAEs.

FURTHER — Our Ongoing Phase 1b Clinical Trial in NSCLC Patients with EGFR Activating Mutations including PACC Mutations

We have completed enrolling patients in FURTHER, an ongoing, global Phase 1b dose escalation and expansion clinical trial being conducted jointly with Allist. It is intended to evaluate the safety, pharmacokinetics and preliminary anti-tumor activity of once-daily firmonertinib when used in patients with NSCLC involving locally advanced or metastatic disease that have previously received systemic therapy and whose tumors contain EGFR activating mutations. Anti-tumor activity is measured by confirmed complete response, defined as the disappearance of all target lesions, or partial response, defined as at least a 30% decrease in target lesions in the absence of a complete response, relative to the total number of patients. The pharmacokinetics, adverse events, serious adverse events, and observed anti-tumor activity in the exon 20 patients of firmonertinib in the clinical trial to date are consistent with those observed in the FAVOUR clinical trial conducted in China. The FURTHER clinical trial includes a cohort of 60 patients with a PACC EGFRm who are TKI treatment-naïve, and has been fully enrolled. In September 2025, we announced our final data from the FURTHER trial of firmonertinib in first-line patients with locally advanced or metastatic EGFRm NSCLC with PACC mutations. In this final readout, patients treated with 240 mg of firmonertinib were observed to experience 16.0 months mPFS and 14.6 months median duration of response. Further, 68.2% of patients treated in first-line at 240 mg and 43.5% of patients treated in first-line at 160 mg were observed to experience a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression as measured by RECIST 1.1 criteria, which measurement of reduction is the threshold in this trial for determination of the ORR. In addition, 47% (n=8/17) of patients with brain metastases at baseline were observed to experience a confirmed response utilizing modified RECIST 1.1 and 42.9% (n=6/14) of first line patients with brain metastases at baseline were observed to experience a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression as measured by RECIST 1.1 criteria. Firmonertinib was generally well-tolerated and consistent with interim safety results.

ALPACCA — Our Ongoing Phase 3 Clinical Trial in First-Line Non-Squamous Locally Advanced or Metastatic EGFRm NSCLC Patients with PACC Mutations

In December 2025, we announced the first patient dosed and plan to enroll 480 patients in ALPACCA, a global, pivotal Phase 3 clinical trial of firmonertinib in first-line non-squamous locally advanced or metastatic NSCLC patients with PACC mutations being conducted jointly with Allist. Our ALPACCA clinical trial is designed to assess the safety and efficacy of firmonertinib administered at 240 mg, once-daily as compared to an investigator's choice of osimertinib or afatinib. The co-primary endpoints of this study are ORR and PFS. The study design reflects design elements from the FDA's Project FrontRunner where we have the potential to seek accelerated approval based on ORR and full approval based on PFS.

Planned Adjuvant Study in NSCLC Patients with Uncommon EGFRm, including Exon 20 Insertion and PACC Mutations

The potential for EGFR TKIs that have demonstrated efficacy, safety and tolerability in the metastatic setting to improve disease-free and overall survival when administered in the adjuvant setting has been demonstrated by osimertinib in NSCLC patients with a classical EGFRm. We believe firmonertinib similarly has the potential to improve outcomes when administered as adjuvant therapy to EGFRm NSCLC patients with uncommon EGFRm, as these patients are not eligible for treatment with osimertinib. We intend to participate in a global adjuvant study of firmonertinib in EGFRm NSCLC with uncommon mutations initiated in China, or to conduct a parallel study, depending on results obtained from currently ongoing clinical trials.

FURLONG — Completed Phase 3 Clinical Trial in Classical EGFRm First-Line NSCLC Patients

FURLONG was a 358-patient clinical trial in China conducted by Allist, with results first reported in 2022, which resulted in the approval of firmonertinib in China as a first-line therapy in patients with locally advanced or metastatic NSCLC with classical EGFRm. It was designed to compare the safety and efficacy of once daily dosing of 80 mg firmonertinib to 250 mg gefitinib. Firmonertinib demonstrated clinically meaningful and statistically significant efficacy and a favorable safety profile as compared to the first-generation EGFR TKI gefitinib. Importantly, firmonertinib exhibited superior efficacy in the treatment of CNS metastases, producing a confirmed CNS metastases specific ORR, which measured reduction in tumor size of at least 30% in brain metastases if present at the start of therapy, of 91%

versus 65% for gefitinib among participants with measurable metastatic CNS disease, demonstrating firmonertinib's ability to cross the blood-brain barrier.

Our Antibody Drug Conjugate Collaborations

Consistent with our focus on curating a pipeline of innovative, impactful oncology therapies across modalities, we are advancing next-generation ADCs. ADCs are a promising modality for treating cancer due to their ability to target chemotherapy directly to the tumor cells. We are using Aarvik's proprietary multi-target, multivalent site-specific conjugation antibody platform to discover and develop ADCs with potentially improved activity and safety over single target bivalent ADCs. We identified a preclinical candidate ARR-002 and have initiated Investigational New Drug (IND)-enabling activities. We are also working with Alphamab to leverage their proprietary linker-payload platform and glycan-conjugation technology to discover, develop, and commercialize ADCs for the treatment of cancers. Pursuant to the Lepu Biopharma Agreement, we are developing ARR-217, a novel CDH17-targeting ADC for the treatment of gastrointestinal cancers, which is currently in Phase 1 clinical development.

Our Team and Approach

We were founded and acquired the rights to develop and commercialize firmonertinib worldwide, with the exception of greater China, which includes mainland China, Hong Kong, Macau and Taiwan, in 2021. We believe that our deep expertise in developing oncology drugs, executing cross border business transactions and track record building companies will allow us to expand our portfolio globally, across the oncology landscape. Our co-founder, Chief Executive Officer and Chairman is Zhengbin (Bing) Yao, Ph.D. Prior to ArriVent, Dr. Yao was Chief Executive Officer and Chairman of Viela Bio, Inc. (Viela), which he co-founded in 2018 by licensing a portfolio of therapeutics from AstraZeneca. Viela was subsequently acquired by Horizon Therapeutics plc in 2021 for $3.1 billion. Prior to Viela, Dr. Yao served as Senior Vice President at MedImmune, Inc. and as Senior Vice President and Head of the Immuno-Oncology Franchise at AstraZeneca. Our other co-founder and President of Research and Development is Stuart Lutzker, M.D., Ph.D. Dr. Lutzker joined from Genentech, Inc., where he served in a number of senior Research and Development roles. Most recently, Dr. Lutzker was Vice President and Head of Oncology, Early Clinical Development and oversaw the early clinical phase development of a number of approved products. See "Certain Relationships and Related Transactions, and Director Independence" for more information.

Our team's deep knowledge in oncology has allowed us to identify novel therapeutic programs with strong biologic and scientific rationale that we believe have the potential to offer a differentiated profile to treat cancer patients. Based on our extensive experience working with regulatory agencies, we will pursue assets that we believe have a clear regulatory path to approval. We believe our highly selective in-licensing strategy provides us with high-quality development candidates at preclinical or clinical stages, which, if approved, would have the potential to achieve global commercial success.

While we source candidates from across the globe, our initial focus has been on compounds originally developed in China. We believe that as the world's second-largest pharmaceutical market, with extensive biopharmaceutical research and development capabilities, China provides us with attractive opportunities to in-license innovative therapies that otherwise may not reach global populations. We believe our business development acumen positions us to build a highly competitive pipeline that we are uniquely positioned to bring to global patient communities, beginning with our lead development asset, firmonertinib.

Our Strategy

We intend to become a leading biopharmaceutical company through the identification, development and commercialization of differentiated medicines to address the unmet medical needs of patients with cancers. To accomplish this objective, we plan to:

Maximize the potential of firmonertinib — develop and commercialize firmonertinib for the treatment of a broad array of EGFRm NSCLC indications.

- *Advance firmonertinib through the pivotal Phase 3 FURVENT clinical trial and seek approval as a first-line therapy for non-squamous locally advanced or metastatic EGFRm NSCLC patients with exon 20 insertion mutations*. Exon 20 insertion mutations represent one of the most prevalent uncommon EGFR mutations and make up over 9% of the EGFR NSCLC patient population. While the antibody amivantamab has been approved as second-line therapy and chemotherapy in combination with amivantamab approved in first line therapy, no TKI has been approved as first-line therapy in this indication. We believe the interim data obtained as of June 15, 2023 in the Phase 1b FAVOUR clinical trial, in which patients were administered a 240 mg once-daily dose of firmonertinib, supports the progression of firmonertinib to the next phase of clinical trials. In that interim data readout, 79% of treatment naïve patients (n=22 out of 28 patients) were observed to experience a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression as measured by RECIST 1.1 criteria. This measurement of reduction is the threshold in this trial for a partial response and for inclusion in determination of the ORR, which is the primary endpoint of this trial. We received Breakthrough Therapy Designation for firmonertinib for the treatment of this disease from the FDA in October 2023, and Orphan Drug Designation for treatment of NSCLC with EGFRm or HER2 mutations or HER4 mutations in February 2024. We do not currently intend to conduct a Phase 2 trial in first-line non-squamous locally advanced or metastatic EGFRm NSCLC patients with exon 20 insertion mutations. We have completed enrollment in our global, pivotal Phase 3 FURVENT clinical trial in first-line non-squamous locally advanced or metastatic EGFRm NSCLC patients with exon 20 insertion mutations and we expect topline data from this clinical trial in mid-2026.
- *Continue to advance firmonertinib through the pivotal Phase 3 ALPACCA clinical trial in EGFRm NSCLC patients with PACC mutations.* We are also advancing the clinical development of firmonertinib as a potential treatment for EGFRm NSCLC patients with PACC mutations. PACC mutations are a distinct set of approximately 70 EGFR-activating mutations, associated with over 12% of EGFRm NSCLC patients. Guidelines employing TKIs for many of the PACC-specific EGFR mutations are not established and, as a result, chemotherapy is often used as the default course of therapy, offering limited efficacy and introducing chemotherapy-related toxicity. Osimertinib is frequently used in some patients, but the activity of osimertinib in such patients is much less than its activity in classical EGFR mutant NSCLC. Afatinib, a second-generation TKI, is also used in some patients, but has an unfavorable safety profile and is not brain penetrant. We are investigating the use of firmonertinib to treat a broad set of PACC mutations the ALPACCA clinical trial based on firmonertinib's observed activity against PACC mutations in preclinical studies together with the evaluation of firmonertinib in multiple clinical trials with an aggregate patient population of over 1000 patients, including over 450 patients outside China. We have initiated our pivotal Phase 3 ALPACCA study with our first patient dosed in December 2025.
- *Evaluate the clinical benefit of treating early-stage disease with firmonertinib.* We also intend to participate in a global registrational Phase 3 clinical trial initiated in China, or to conduct a parallel study, to investigate the potential benefit of firmonertinib in the adjuvant setting in NSCLC patients with uncommon EGFRm that are not eligible for osimertinib such as exon 20 insertion and PACC mutations. We intend to join the adjuvant study of firmonertinib, or to conduct a parallel study, once the EGFRm patient group is further defined based on ongoing clinical trials in the metastatic setting.
- *Employ combination strategies with firmonertinib to overcome and prevent resistance to EGFR TKI in NSCLC involving classical mutations.* Acquired resistance presents an inevitable challenge to longer-term EGFRm NSCLC management. As such, we are evaluating the use of firmonertinib in combination with other potential agents to extend patient benefit in EGFRm NSCLC patients.

Advance novel therapeutic product candidates for unmet medical needs, leveraging innovative platforms and technologies starting with ADCs.

- *Discover and develop differentiated next-generation ADCs for solid tumors.* ADCs are a promising modality for treating cancer due to their ability to target chemotherapy directly to the tumor cells. We have entered into a research collaboration with Aarvik to leverage its proprietary multi-target, multivalent, site-specific conjugation antibody platform to discover ADCs with potentially improved activity and safety over single target bivalent ADCs for oncology indications globally. We identified a preclinical candidate, ARR-002, and have initiated IND-enabling activities. We have also entered into a collaboration with Alphamab to discover, develop and commercialize novel ADCs. We are working with Alphamab to leverage their proprietary linker-payload platform and glycan-conjugation technology to identify novel ADCs for oncology indications globally, except greater China, which includes mainland China, Hong Kong, Macau and Taiwan where Alphamab retains the right to develop and commercialize ADCs. We entered into a license agreement with Lepu Biopharma pursuant to which Lepu Biopharma granted us a right to develop and commercialize ARR-217, an antibody drug conjugate targeting CDH17 for gastrointestinal cancers outside greater China, which is mainland China, Hong Kong, Macau and Taiwan.

  ARR-217 is currently enrolling patients in a Phase 1 clinical study. This is an open-label, multi-center, Phase 1 study to evaluate the safety, tolerability, efficacy, and pharmacokinetics of ARR-217 (MRG007) in patients with unresectable locally advanced or metastatic solid tumors.

Broaden our pipeline through expanded business development initiatives.

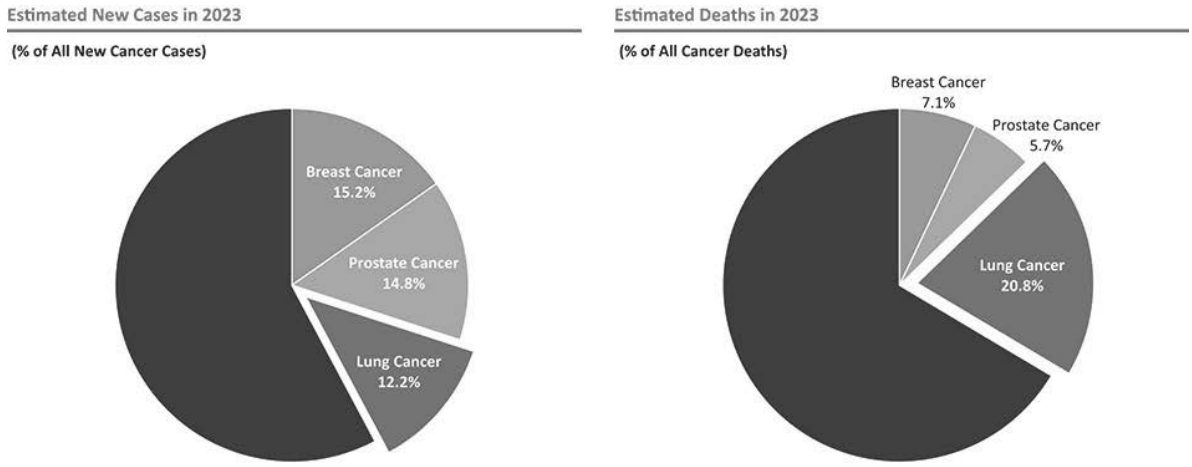
- *Acquire rights to additional therapeutic candidates targeting solid tumors.* We intend to use our demonstrated capabilities in business development to establish additional collaborations and acquire the rights to drug candidates designed to treat solid tumors and address significant unmet medical needs of patients with cancers. While we source candidates from across the globe, our initial focus has been on drugs originally discovered and developed in China for potential commercialization in the United States, the European Union, and other jurisdictions. For programs that we in-license, we plan to pursue a global development strategy to enable approval and commercialization in a broad set of geographies. We remain agnostic as to therapeutic modality, which we believe will expand our access to drug candidates with attractive therapeutic profiles.

- *Track record of establishing collaborations and license agreements.* Since our inception in 2021, we have established four licensing agreements for oncology assets, including our lead product candidate firmonertinib, and the ADC product candidates ARR-217, ARR-002, ARR-421 and ARR-173. We believe in continuing to build our pipeline through sourcing innovation globally and remaining nimble in developing such programs in collaboration with our partners.

Lung Cancer

According to the National Cancer Institute, lung cancer is predicted to account for nearly 250,000 of the two million new cancer diagnoses made in the United States in 2023. Lung cancer ranks behind both breast and prostate cancer in terms of the number of newly diagnosed cases yet is responsible for far more deaths than any other type of cancer, with the estimated 27,000 lung cancer deaths to occur in 2023, more than double the annual number of deaths attributed to colorectal, pancreatic or breast cancer, as illustrated in the chart below. Lung cancer is the cause of approximately 20% of all cancer-related deaths and the 5-year survival rate for advanced lung cancer in the United States is approximately

6%. Worldwide, lung cancer is estimated to be responsible for 2.2 million new cancer cases annually and 1.8 million deaths.

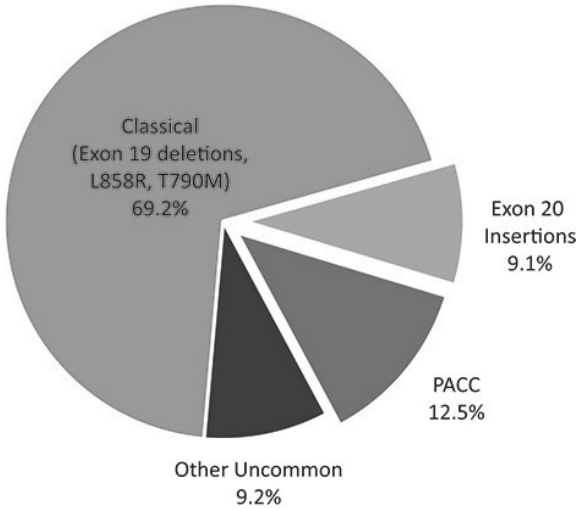


Non-Small Cell Lung Cancer and the EGFR Driver Mutation

Cases of lung cancer are divided into NSCLC and small cell lung cancer, with NSCLC accounting for approximately 85% of all lung cancer diagnoses. NSCLC can be further segregated into two primary classifications: non-squamous cell carcinoma and squamous cell carcinoma. Non-squamous cell carcinoma is the most prevalent type of NSCLC and makes up approximately 77% of all NSCLC cases. Adenocarcinoma is the largest subgroup of the non-squamous NSCLC, constituting 81%. Among the genetic mutations that promote the development of NSCLC, mutational activation of the EGFR gene is among the most common. EGFR is a transmembrane glycoprotein consisting of an extracellular epidermal growth factor binding domain, a hydrophobic transmembrane domain and an intracellular tyrosine kinase domain that regulates signal transduction pathways involved in cellular proliferation. Its mutation results in the constitutive activation of these pathways and uncontrolled growth of the cancer cell. The overall prevalence of the EGFR mutation among NSCLC patients varies widely between different ethnic populations. Approximately 38% of NSCLC patients from Asian countries have an EGFR mutation, while approximately 24% of NSCLC patients in the Americas and approximately 14% of NSCLC patients in Europe have EGFR mutations. EGFR mutations are also more commonly associated with NSCLC patients who have never smoked, as well as women and young adult NSCLC patients. Substantially all NSCLC cases involving an EGFR mutation are non-squamous cell carcinomas.

Numerous EGFR mutations have been identified that cluster within the EGFR kinase domain encoded by exons 18-21 in the EGFR gene. These mutations, which include amino acid insertions, deletions and substitutions, activate EGFR signaling within the tumor cell and can be categorized as either classical or uncommon mutations. Classical mutations involving a deletion in amino acids encoded by exon 19 and another involving a substitution of the amino acid arginine for leucine at codon 858, which is referred to as an L858R mutation, are responsible for approximately 69% of NSCLC patients with an EGFRm. The uncommon mutations may be categorized based on the structural change to the drug binding pocket of the EGFR kinase domain, with the two most frequent groups of uncommon mutations involving an exon 20 insertion or PACC mutations of the EGFR. These two types of uncommon mutations account for approximately 22% of patients with EGFRm NSCLC and the life expectancy for NSCLC patients with uncommon EGFRm, including exon 20 insertion and PACC mutations, is lower. The distribution of patients with EGFR-mutation positive NSCLC is presented below. EGFRm are detected by numerous commercially available FDA-approved DNA tests, either Polymerase Chain Reaction (PCR) or Next Generation Sequencing (NGS), utilizing either tumor tissue or blood samples and testing for EGFRm, as well as other activating gene mutations, is considered standard in the management of NSCLC as per national guidelines such as National Comprehensive Cancer Network (NCCN). We are working with a diagnostics company to develop an FDA-approved NGS test for confirming EGFR exon 20 insertion mutations in our clinical trial and if firmonertinib is approved, we believe it would be indicated for patients with EGFRm as detected by an FDA-approved DNA test.

EGFR activating mutations include both classical and uncommon mutations in the kinase domain



Current Therapeutics and their Limitations

In classical EGFRm NSCLC, the current standard of care for the treatment of locally advanced or metastatic EGFRm NSCLC involves the use of a TKI as first-line therapy. Two first-generation TKIs, gefitinib and erlotinib (TARCEVA®), received initial marketing approval by the FDA in the early 2000s. These drugs, which were designed to competitively bind with EGFR at the ATP-binding site in a reversible manner to block enzymatic activation and downstream signal transduction, provide certain NSCLC patients with EGFRm substantial benefit, offering superior efficacy and safety profiles as compared to chemotherapy. However, durability of response to treatment is limited and virtually all patients with advanced disease acquire resistance, the most common of which involves a T790M substitution mutation. In addition, rash and diarrhea, often severe, are common adverse events (AEs). Efforts to address acquired resistance to first-generation TKIs led to the approval by the FDA of the second-generation TKIs afatinib (GILOTRIF®) in 2013 and dacomitinib (VIZIMPRO®) in 2018, drugs which irreversibly block the tyrosine kinase activity. However, TRAEs are more pronounced than the first-generation designs, which have limited broader clinical application of the second-generation TKIs.

Osimertinib was the first third-generation TKI to receive FDA approval and is currently a standard of care for patients with EGFRm NSCLC involving classical mutations and the related treatment emergent T790M mutation in the majority of countries worldwide. Osimertinib provides an improved AE profile, including a reduction in severe adverse events, compared to the earlier generation EGFR targeted TKIs and displays a greater ability to cross the blood-brain barrier, enabling efficacy against metastases involving the CNS. The ability to treat CNS metastases is of notable importance as patients with EGFR-activating mutations are particularly susceptible to the development of brain metastases, which can occur in up to 70% of patients during the course of their disease. In 2024, amivantamab in combination with lazertinib was approved for the treatment of first-line NSCLC patients with EGFR exon 19 deletions

or exon 21 L858R substitution mutations. Amivantamab is a bispecific antibody and lazertinib is a third-generation EGFR TKI. The key limitations of therapies in EGFRm NSCLC are presented in the graphic below:

Agents	First Approval Year	EGFR Mutation Indications			Key Limitations
		Exon 20 Insertions	PACC	Classical	
Gefitinib, Erlotinib	2003, 2004			✓	Limited efficacy and tolerability, generates T790M resistance mutations
Afatinib	2013		*	✓	Tolerability (rash and diarrhea), low to no brain penetration
Osimertinib	2015			✓	Limited activity outside of Exon 19 deletion and L858R mutations
Amivantamab	2021	✓		✓	IV administration, tolerability (rash and nail toxicity) severe infusion reactions, low to no brain penetration
Mobocertinib	2021	**			Low response rates, tolerability (diarrhea), black box warning for QT prolongation, low to no brain penetration

Table includes approved and disclosed registrational indications

* *Afatinib has limited clinical data in patients with 2 of the 70 described PACC mutations.*

** *Exclaim-2 study in 1L announced as negative and in July 2024, the FDA withdrew the license for mobocertinib in the United States*

Dacomitinib is also approved in the United States for classical EGFR mutations

There is currently no TKI approved as first-line therapy for NSCLC patients with EGFR exon 20 insertion mutations. Platinum-based chemotherapy with pemetrexed is a standard of care for first-line therapy in this patient population in the United States and the European Union with or without amivantamab. Of particular note, approximately one-third of NSCLC patients harboring EGFR exon 20 insertion mutations have brain metastases at the time of diagnosis, which are mainly treated with radiation therapy, as chemotherapy is less effective in the treatment of brain metastases due to low brain penetration.

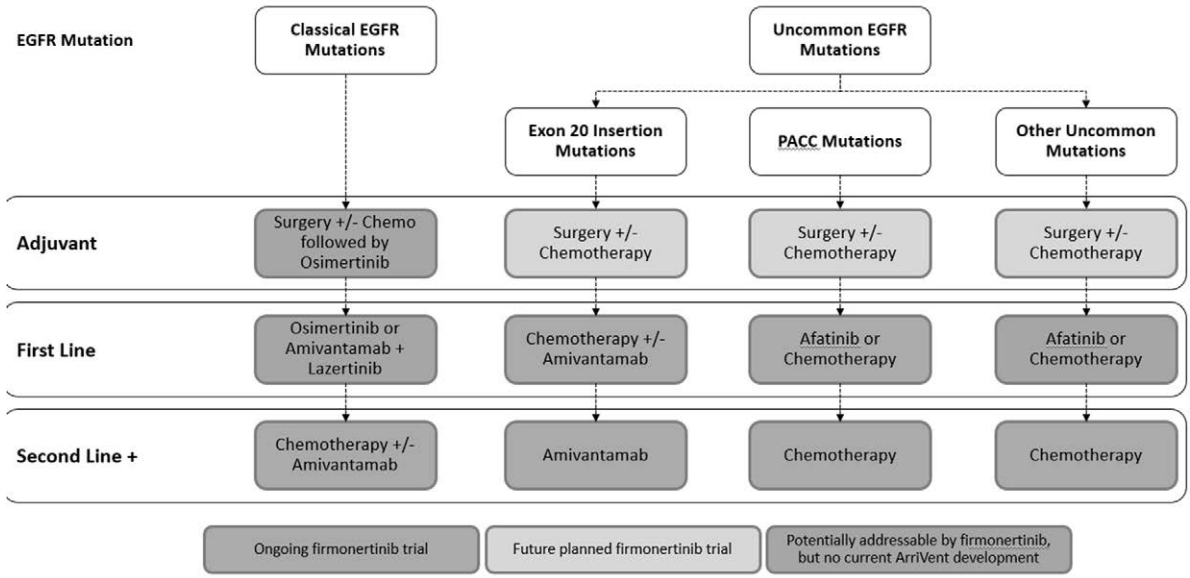
In 2021, the FDA granted marketing approval to two therapeutics, mobocertinib, a TKI, and amivantamab, a bispecific antibody, to treat NSCLC patients with exon 20 insertion mutations which have progressed after administration of platinum-based chemotherapy. Both approvals were granted under accelerated approval and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Notably, in July 2023, Takeda announced the discontinuation of its Phase 3 clinical trial of mobocertinib as a monotherapy in first-line patients due to futility and subsequently withdrew the drug from the market globally. In August 2023, Johnson & Johnson announced that its Phase 3 trial of amivantamab in combination with chemotherapy in first-line patients met its primary endpoint of PFS when compared to chemotherapy alone. While the FDA approved the use of this combination in this patient population in March 2024, and by the European Commission in July 2024, the use of chemotherapy in combination with amivantamab in the first-line patients may be limited due to the need to combine with intravenous chemotherapy and lack of brain penetration of amivantamab, along with chemotherapy associated toxicities.

A distinct set of approximately 70 uncommon EGFR-activating mutations have been identified that are predicted to alter the orientation of the interior surface of the ATP-binding pocket of the EGFR P-loop or αC-terminal end of the C-helix within the tyrosine kinase domain and are referred to as PACC mutations. Over 12% of patients with EGFRm are estimated to involve PACC mutations and patients diagnosed with PACC mutations have limited treatment options. Guidelines employing TKIs for many of the PACC-specific EGFRm are not established and as a result chemotherapy is used as the default course of therapy in many patients with limited clinical benefit. Osimertinib is frequently used in some patients, but the activity of osimertinib is much less than in classical EGFRm NSCLC. The second-generation TKI

afatinib is the only TKI to have received FDA and the European Medical Association approval in NSCLC to treat EGFRm NSCLC with limited clinical data for two of the 70 PACC mutations, G719X and S768I.

The current treatment paradigm for the various subtypes of EGFRm NSCLC outside of China and areas of unmet medical needs where we believe firmonertinib may provide clinical utility is summarized in the chart presented below.

Firmonertinib has the potential to address significant unmet needs in the current EGFRm NSCLC treatment paradigm



Specific to the HER2 exon 20 insertion mutation, an exon 20 insertion in the related HER2 gene, in August 2022 the FDA granted accelerated approval to fam-trastuzumab deruxtecan-nxki (ENHERTU®), a HER2-directed antibody-drug conjugate, for adults with unresectable or metastatic NSCLC who have received prior systemic therapy. Despite its approval, patients with refractory or recurrent disease remain a significant portion of the patient population and currently approved TKIs have demonstrated limited efficacy in targeted HER2 exon 20 insertion mutations.

Firmonertinib: Our Lead Development Candidate

Our lead development candidate is firmonertinib, an investigational, novel, EGFR mutant-selective TKI that we are developing for the treatment of patients with NSCLC harboring a broader set of EGFRm than are currently served by approved EGFR TKIs. Firmonertinib is currently approved and commercially distributed by Allist in China as a first-line treatment of locally advanced or metastatic NSCLC patients with classical EGFRm as well as pre-treated patients with T790M mutations. In addition, in an interim data readout from the FAVOUR trial of firmonertinib, reductions in tumor size have been observed in patients with exon 20 insertion mutations and activity in PACC mutations has been observed in an interim data readout from the FURTHER trial. Exon 20 insertion mutations and PACC mutations are each a subtype of uncommon mutation. Exon 20 insertions and PACC mutations account for approximately 22% of EGFRm NSCLC patients and are largely underserved by existing treatments. Firmonertinib has been studied in over 1000 patients, including over 450 patients outside China, across a broad dose range. We anticipate that favorable safety data, if obtained for firmonertinib, could allow for the administration of firmonertinib at different doses required for optimal activity in different EGFRm patient populations. Encouraging activity has been observed to date in both preclinical and clinical settings, including response in CNS metastases, in an interim data readout from our partner's ongoing FAVOUR clinical trial in China with patients with exon 20 insertions, and in the FURTHER clinical trial in patients with PACC mutations globally.

Of particular note, firmonertinib exhibited elevated tissue distribution to the brain in preclinical studies. In these studies, the brain and plasma concentrations were measured in mice following a single dose of either firmonertinib or

osimertinib and the brain-to-plasma calculated for both total drug (Kp) and unbound drug (Kp uu). Osimertinib was used as a reference compound in certain experiments as it has demonstrated clinical activity in patients with CNS metastases. As is noted in the chart below, these experiments showed that firmonertinib penetrated the blood-brain barrier at a rate similar to that of osimertinib.

Firmonertinib displayed brain penetrant properties similar to osimertinib in pre-clinical studies. When mice were administered a single dose of either firmonertinib or osimertinib, they penetrated the blood-brain barrier to a similar extent.

Drug	Species	Brain/Plasma Ratio (Kp)	Kp,uu (Unbound Brain/Plasma Ratio)
Furmonertinib*	Mice (B-NDG)	3.31	0.87
AST5902 (Active metabolite)*		0.76	0.14
Osimertinib	Nude mice	1.8[a]/2.8[b]	0.21

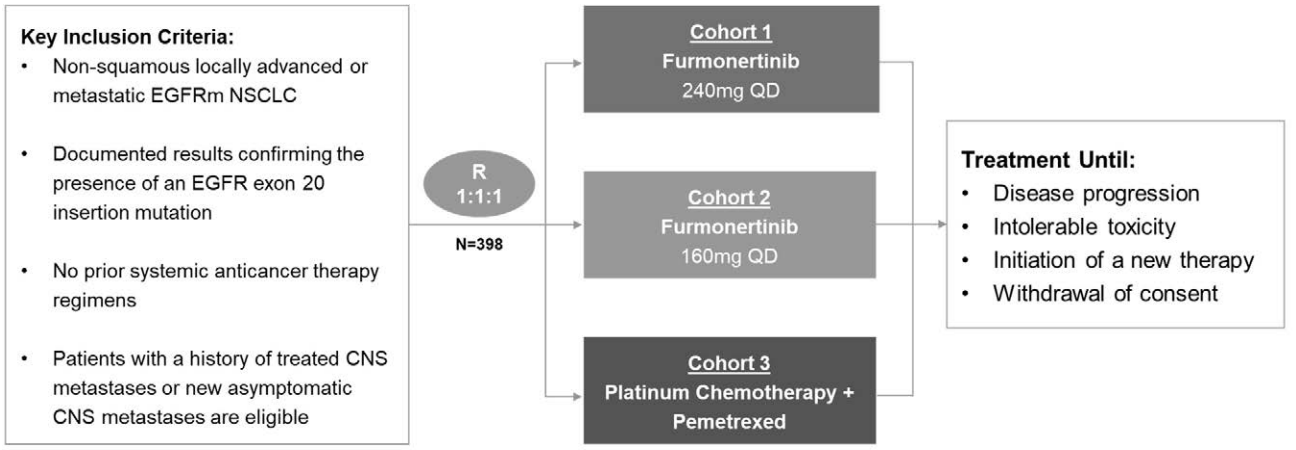
*Generated by Medicilon; [a] Yates et al, Clin Cancer Res; 22(20); 5130–40. [b] Colclough et al, Clin Cancer Res 2021;27:189–201.

We are currently awaiting topline data from our FURVENT clinical trial, a global, pivotal Phase 3 clinical trial of firmonertinib in first-line non-squamous locally advanced or metastatic NSCLC patients with exon 20 insertion mutations and we expect topline data in mid-2026. In addition, we are conducting our ALPACCA trial, a global, pivotal Phase 3 clinical trial of firmonertinib in first-line non-squamous locally advanced or metastatic NSCLC patients with PACC mutations. Data from our clinical trials are discussed below.

FURVENT — Our ongoing Phase 3 Clinical Trial in First-Line Non-Squamous Locally Advanced or Metastatic EGFRm NSCLC Patients with Exon 20 Insertion Mutations

We have completed enrolling patients in FURVENT, a global, pivotal Phase 3 clinical trial of firmonertinib in first-line non-squamous locally advanced or metastatic EGFRm NSCLC patients with exon 20 insertion mutations being conducted jointly with Allist. We designed a randomized clinical trial, integrating feedback from global regulatory agencies, that consists of three cohorts, which enrolled 398 patients in total, designed to evaluate the safety and efficacy of firmonertinib at two different dose levels, 160 mg and 240 mg, administered daily (QD) and compare therapeutic benefit to platinum-based chemotherapy cycles with pemetrexed, the clinical trial's active control group. Participants in this clinical trial will continue to receive treatment until disease progression or discontinuation related to toxicity, with patients in the control group allowed to cross over into one of the two firmonertinib arms after disease progression. The primary endpoint of this trial is PFS per blinded independent central review utilizing RECIST 1.1 criteria. Secondary endpoints include ORR, overall survival (OS) and DOR, as well as brain-specific ORR and PFS in patients with brain metastases. We have completed enrolling patients in this clinical trial and anticipate top-line data for the use of

firmonertinib as first-line therapy in patients with non-squamous locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations in mid-2026. The FURVENT clinical trial's study design is illustrated below:

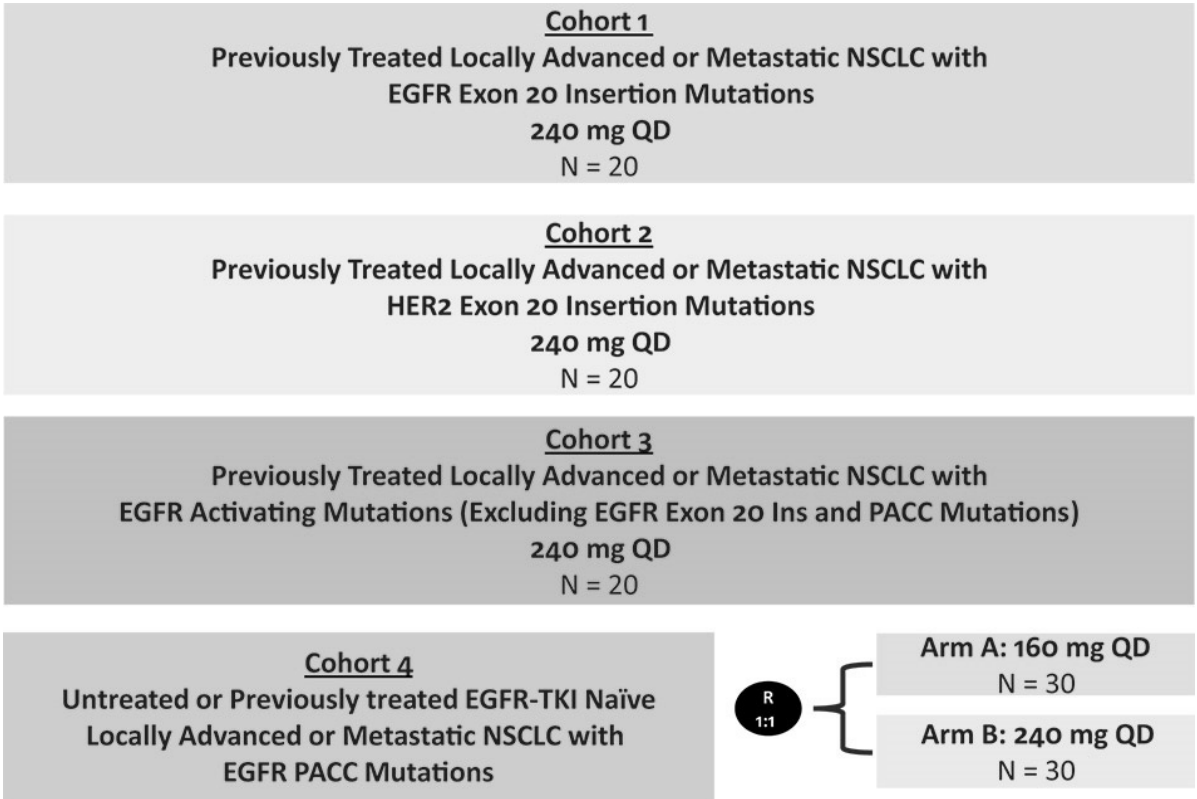


Primary endpoint: PFS by Blinded Independent Central Review (BICR)
Secondary endpoint: OS, ORR, DOR, CNS-PFS, CNS-ORR, Safety, Pharmacokinetics, Patient Reported Outcomes (PROs)

FURTHER — Our Ongoing Phase 1b Clinical Trial in NSCLC Patients with EGFR Activating Mutations including PACC Mutations

We completed enrolling patients in FURTHER, an ongoing, global Phase 1b dose escalation and expansion clinical trial being conducted jointly with Allist. It is intended to evaluate the safety, pharmacokinetics and reduction in tumor size as a result of once-daily firmonertinib when used in locally advanced or metastatic non-squamous EGFRm NSCLC patients that have previously received systemic therapy and whose tumors contain EGFR activating mutations, including both classical and uncommon, as well as HER2 exon 20 insertion mutations. Cohort 4 specifically enrolls patients with EGFR PACC mutations. PACC mutations represent a group of approximately 70 EGFR activating mutations characterized by a structural displacement of the P-loop and/or αC-helix within EGFR's kinase domain which impact drug binding for third generation EGFR TKIs such as osimertinib. PACC mutations can be identified along with the classical EGFR mutations using commercially available NGS panels. Currently, afatinib, a second-generation EGFR TKI has data supporting its use in two of the approximately 70 PACC mutations (S768I and G719X). Our preclinical data to date suggest that firmonertinib may have activity against a significantly broader number of PACC mutations. The

first stage of the FURTHER clinical trial enrolled a broad group of EGFRm NSCLC patients to evaluate pharmacokinetics and safety in patients outside of China and identify a dose for the expansion cohorts shown below.

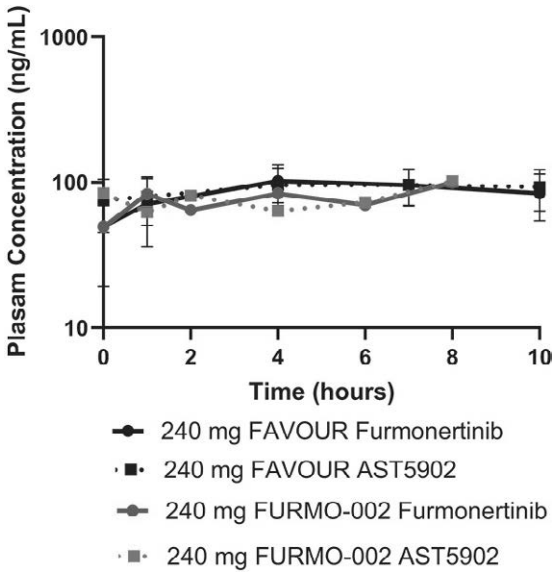


- *Cohort One* is designed to enroll 20 patients with locally advanced or metastatic EGFR exon 20 insertion positive NSCLC who have previously received systemic treatment and may have received prior EGFRm targeting TKI therapeutic or amivantamab. Patients in Cohort One are to receive 240 mg firmonertinib once daily.
- *Cohort Two* is designed to enroll 20 patients with locally advanced or metastatic HER2 exon 20 insertion positive NSCLC, a mutation and patient population that is distinct from the exon 20 mutation and patient population. Patients in Cohort Two will have previously received systemic treatment and are to receive 240 mg firmonertinib once daily.
- *Cohort Three* is designed to enroll 20 patients with locally advanced or metastatic NSCLC with an EGFR-activating mutation other than exon 20 insertion or PACC mutations who have previously received systemic treatment. Patients with classical EGFRm must have received prior osimertinib therapy. Participants in Cohort Three are to receive 240 mg firmonertinib once daily.
- *Cohort Four* is designed to enroll 60 patients with locally advanced or metastatic NSCLC with EGFR PACC mutations who are TKI-treatment naive. Patients in Cohort Four are randomized into two groups, one group of up to 30 patients administered 160 mg firmonertinib once-daily and the other group of up to 30 patients administered 240 mg firmonertinib once-daily.

Pharmacokinetic data obtained in the first stage of the FURTHER clinical trial as of June 15, 2023 were consistent with initial pharmacokinetic data obtained in the FAVOUR clinical trial as of June 15, 2023 with similar steady-state levels of firmonertinib and its major metabolite, AST5902 (see figure below). The AEs in the FURTHER clinical trial have been consistent with the EGFR targeted TKI class in general, with diarrhea, stomatitis and rash being the most commonly observed TRAEs. The frequency of dose reduction and discontinuation due to AEs has remained low. Initial

evidence of reduction in tumor size has been observed, with confirmed and unconfirmed partial responses to firmonertinib noted in NSCLC patients with mutations involving EGFR exon 20 insertions.

Firmonertinib has shown similar drug levels at steady state in both the FAVOUR and the FURTHER clinical trials

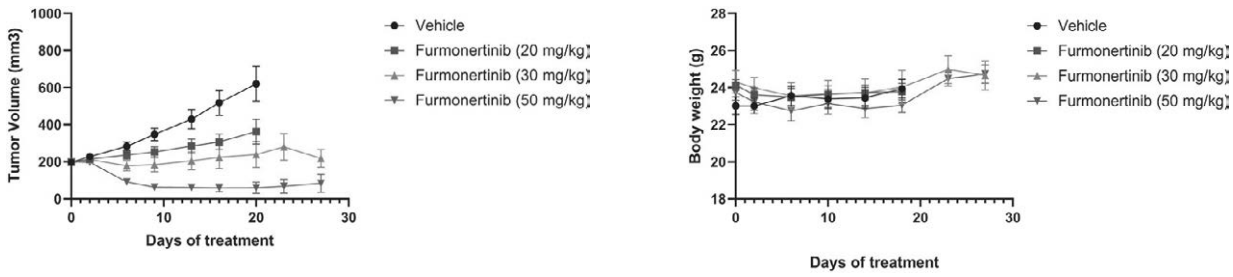


Reduction in tumor size observed in preclinical studies with firmonertinib in uncommon EGFR mutations

We advanced firmonertinib into clinical trials as a potential treatment for EGFR mutation-positive NSCLC involving uncommon mutations based on compelling data demonstrating reduction in tumor size in preclinical studies using mouse xenografts, as presented below.

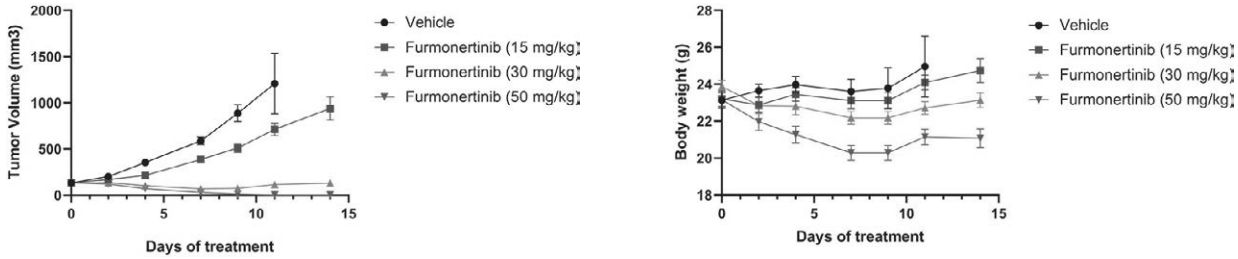
As is detailed in the illustration presented below, in this LU0387 patient derived tumor xenograft model with an EGFR exon 20 insertion mutation H773_V774insNPH, once daily oral dosing of firmonertinib at 20 mg/kg, 30 mg/kg or 50 mg/kg, which equates to an approximate human dose of 40 mg, 160 mg or 240 mg respectively, was observed to induce significant tumor growth inhibition with regression of tumors at the 50 mg/kg dose with minimum change to bodyweight.

Firmonertinib displayed reduction in tumor size in EGFR exon 20 insertion mutations tumor model



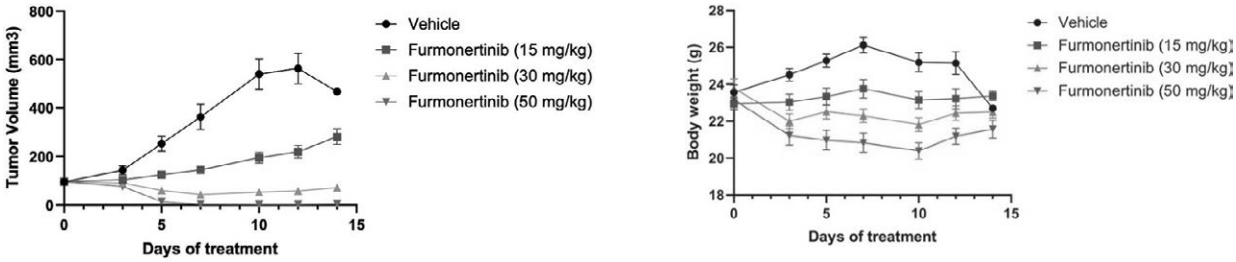
Similar reduction in tumor size was observed in a Ba/F3 subcutaneous tumor xenograft model harboring a G724S PACC mutation as shown below. This PACC mutation is less sensitive to firmonertinib than other PACC mutations based on cell line data. The oral administration of 15 mg/kg, 30 mg/kg or 50 mg/kg firmonertinib one time per day produced pronounced significant inhibition of tumor growth with regression of tumors at the two higher doses. We believe the limited loss of body weight suggests that the drug was generally well tolerated.

Tumor growth inhibition was observed in an EGFR G724S PACC mutation tumor model with firmonertinib



The *in vivo* efficacy of firmonertinib was also evaluated in a subcutaneous Ba/F3 tumor xenograft model with a HER2 exon 20 insertion mutation V777_G778insGC as illustrated below. B-NDG mice administered an oral dose of 15 mg/kg, 30 mg/kg or 50 mg/kg firmonertinib once daily were observed to exhibit significant tumor growth inhibition with regression at the two higher doses. Moreover, firmonertinib appeared generally well tolerated with minimal change in body weight.

Reduction in tumor size was observed in a HER2 exon 20 insertion mutation tumor model with firmonertinib



FURTHER Cohort 4 — Our Ongoing Phase 1b Clinical Trial in NSCLC Patients with EGFR Activating PACC Mutations

The FURTHER clinical trial cohort 4 enrolled 60 patients with locally advanced or metastatic NSCLC with EGFR PACC mutations who are TKI-treatment naive. Patients in Cohort 4 are randomized into two groups, one group of up to 30 patients administered 160 mg firmonertinib once-daily and the other group of up to 30 patients administered 240 mg firmonertinib once-daily. Patients with asymptomatic metastases involving the CNS are allowed to participate in the trial. The primary endpoint of this trial is ORR as measured by the Response Evaluation Criteria In Solid Tumors (version 1.1) by Blinded Independent Central Review. Secondary endpoints include DOR sustained, disease controlled without progression of the disease (DCR), PFS, OS and safety. Follow-up evaluations with trial participants are

conducted every six weeks. The baseline characteristics of the 60 patients enrolled in the FURTHER clinical trial are described in the following table.

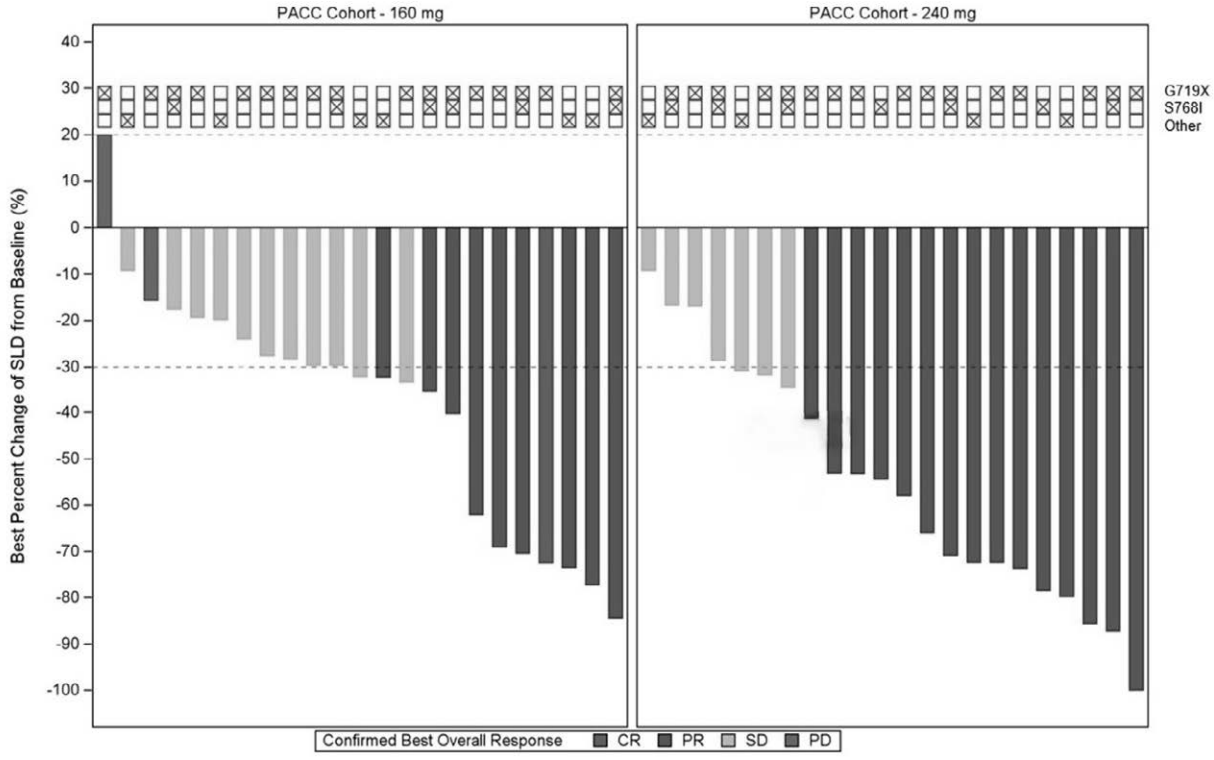
	All PACC Patients		1L PACC Patients	
	160 mg QD n=31	240 mg QD n=29	160 mg QD n=25	240 mg QD n=22
Age (years), median (range)	65.0 (48–86)	68.0 (50–83)	67 (48–86)	67.5 (50–83)
Male / Female, %	32.3 / 67.7	34.5 / 65.5	40.0 / 60.0	36.4 / 63.6
ECOG 0 / 1, %	29.0 / 71.0	27.6 / 72.4	32.0 / 68.0	27.3 / 72.7
Brain Metastases[a], %	32.3	34.5	28.0	31.8
Non-smoker / Former or Current Smoker, %	64.5 / 35.5	79.3 / 20.7	76.0 / 24.0	86.4 / 13.6
Race: Asian / White / Other, %	71.0 / 22.6 / 6.5	72.4 / 20.7 / 6.8	80.0 / 20.0 / 0	77.3 / 13.6 / 9.1
Prior Treatment Type, %				
Chemotherapy	16.1	17.2	4.0	0
Immunotherapy	3.2	13.8	0	4.5[b]

As of June 3, 2025, the final data was available from the 45 patients who have had measurable disease at baseline by blinded independent central review committee (BICR), had received at least two tumor assessments, had progressive disease or death, or discontinued from treatment. Of these 45 patients 22 are in the 240mg first line PACC patient group and 23 are in the 160mg first line PACC patient group. Safety data were available for all 60 patients. Based on these data, reduction in tumor size was observed across all cohorts. Confirmed ORRs by BICR (defined as a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression) were 68% among the 240mg cohort and 43% among the 160 mg cohort. The DCR by BICR, which includes complete responses, partial responses and stable disease, was 100% and 91% for each of these respective trial cohorts, respectively.

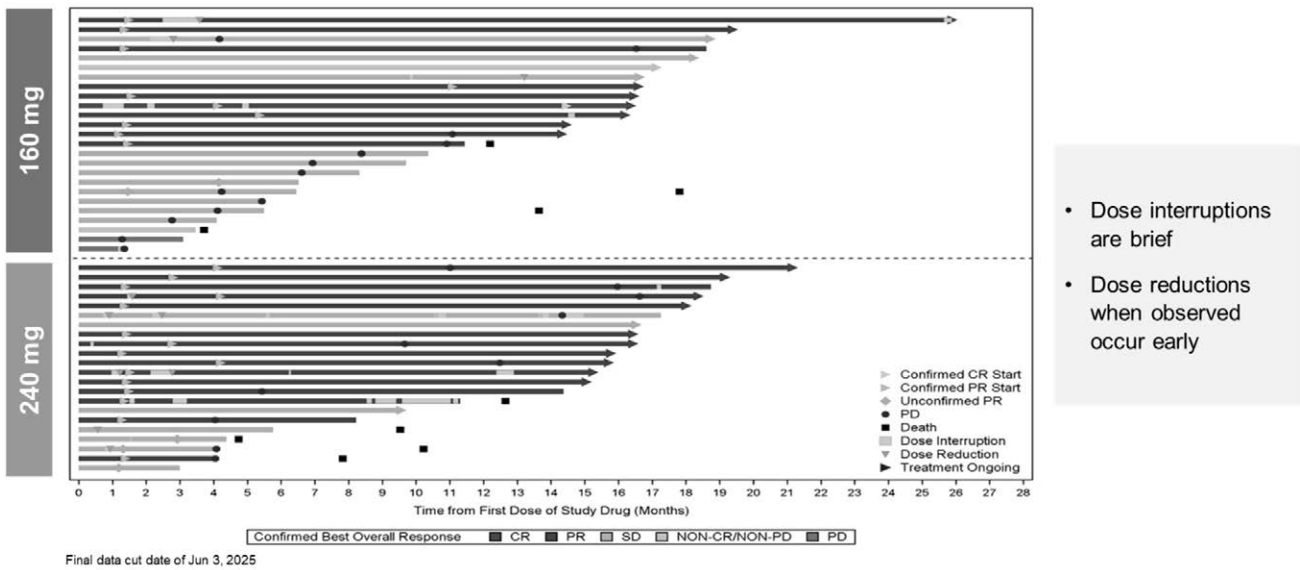
	160 mg QD n=23	240 mg QD n=22
Best ORR, % (95% CI)[a]	**52.2%** (30.6–73.2)	**81.8%** (59.7–94.8)
Confirmed ORR, % (95% CI)	**43.5%** (23.2–65.5)	**68.2%** (45.1–86.1)
Best overall response, n (%)		
Complete response (CR)	1 (4.3%)	0 (0%)
Partial response (PR)	9 (39.1%)	15 (68.2%)
Stable disease (SD)	11 (47.8%)	7 (31.8%)
Progressive disease (PD)	2 (8.7%)	0 (0%)
Median Duration of Response, months	NA	14.6
DCR (CR+PR+SD), % (95% CI)	**91.3%** (72.0% – 98.9%)	**100%** (84.6% – 100%)

The extent of change in tumor size was evaluated across patients and shown in the figure below taken from the final data cut of June 3, 2025. Patients on average achieved greater tumor size reduction in the 240 mg dose versus the 160 mg dose. Tumor size reduction was observed across the different PACC mutations such as frequent (G719X, S78I), less frequent (other), single and compound mutations.

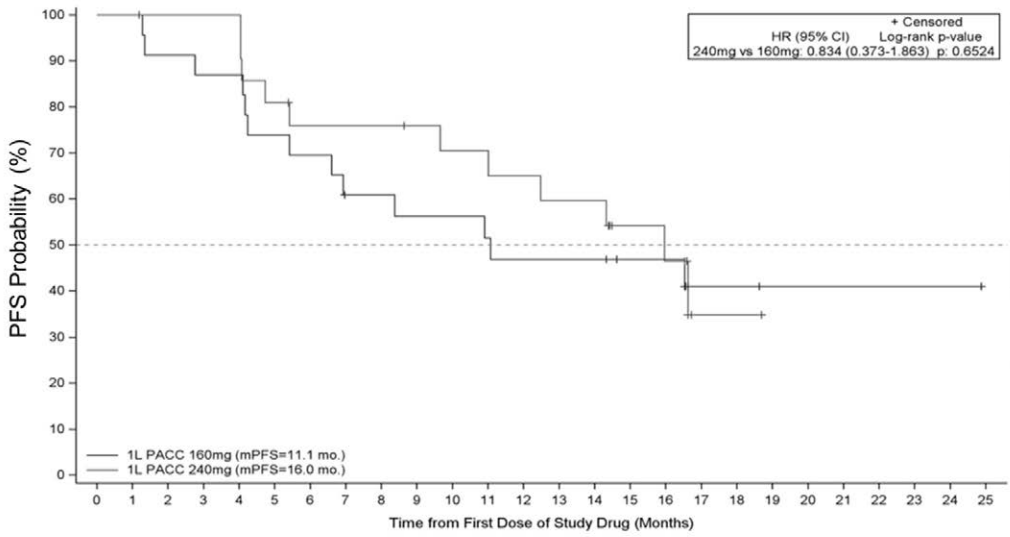
Tumor size reduction was observed in different PACC mutations with firmonertinib



Responses occurred rapidly with most patients having a partial response by the first tumor assessment at six weeks with responses ongoing in many patients as denoted in the figure below.



The confirmed median PFS as of the final data cut of June 3, 2025 was 16.0 months at the 240mg dose and 11.1 months at the 160mg dose. The median duration of follow-up was 16.5 months.



Final data cut as of June 3, 2025 for BICR
Median duration of follow up 16.5 months (95% CI 14.6, 16.6 months)

160 mg QD

11.1 months (6.6, NR)

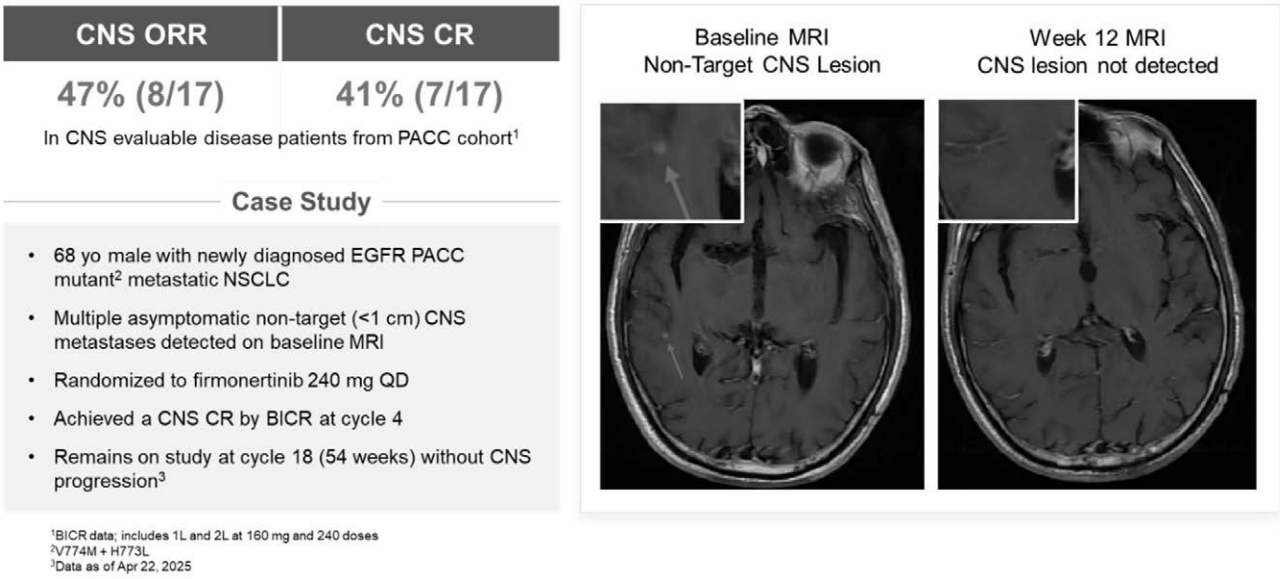
240 mg QD

16.0 months (11.0, NA)

HR (95% CI)

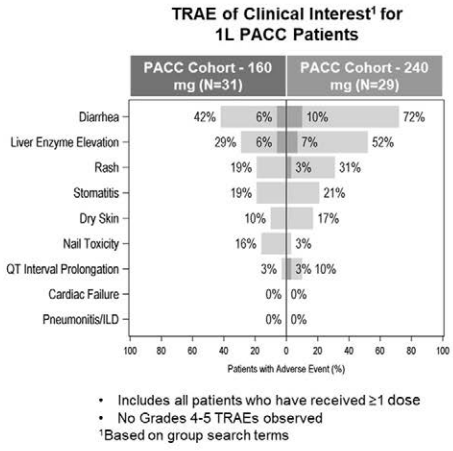
0.834 (0.373 – 1.863), *p* = 0.6524

Confirmed CNS responses were also observed in response evaluable patients as denoted in the figure below.



Firmonertinib was observed to be generally well tolerated and demonstrated safety results similar to prior firmonertinib trials. The table below summarizes this safety and tolerability data collected in the FURTHER trial as a whole and in Cohort 4 specifically, as of the final data cut date of June 3, 2025:

	All PACC Patients		All Patients in FURTHER	
Treatment-related adverse events (TRAEs), n (%)	**160 mg (N=31)**	**240 mg (N=29)**	**160 mg (N=42)**	**240 mg (N= 116)**
TRAEs any grade	28 (90.3)	28 (96.6)	36 (85.7)	101 (87.1)
TRAEs Grade ≥3	8 (25.8)	6 (20.7)	9 (21.4)	25 (21.6)
Treatment-related serious AEs (SAEs)	2 (6.5)	1 (3.4)	3 (7.1)	11 (9.5)
Dose interruption	9 (29.0)	11 (37.9)	13 (31.0)	45 (38.8)
Dose reduction	6 (19.4)	7 (24.1)	7 (16.7)	24 (20.7)
Dose discontinuation	1 (3.2)	0	2 (4.8)	8 (6.9)



FAVOUR — Phase 1b Clinical Trial in NSCLC Patients with EGFR Exon 20 Insertion Mutations

The FAVOUR clinical trial is a 90-patient, Phase 1b clinical trial being conducted by Allist in China that is intended to assess the safety and efficacy of firmonertinib in locally advanced or metastatic NSCLC patients who have EGFR exon 20 insertion mutations. This 90-patient clinical trial consists of 3 treatment cohorts of 30 patients each. Eligibility criteria include both adult patients with one or more measurable lesions who are either treatment-naïve, or first-line patients, or have previously received systemic therapy. Patients with asymptomatic metastases involving the CNS are allowed to participate in the trial. First-line patients receive 240 mg firmonertinib once daily. Patients that have received prior treatment are randomized to receive either 160 mg or 240 mg of firmonertinib once daily. The primary endpoint of this trial is ORR as measured by the RECIST version 1.1 by BICR. Secondary endpoints include DOR, DCR, PFS,

overall survival (OS) and safety. OS is not reported due to the data being immature as of the data cutoff date of June 15, 2023. Follow-up evaluations with trial participants are conducted every six weeks. In the treatment-naïve population, firmonertinib is being evaluated as a first-line therapy. The baseline characteristics of the 86 patients enrolled in the FAVOUR clinical trial as of June 15, 2023 are described in the following table.

	Treatment Naïve 240 mg N=30	Previously Treated 240 mg N=28	Previously Treated 160 mg N=28
Age, Median (Min, Max) (years)	61.5 (33, 73)	55.5 (33, 73)	58.5 (22, 77)
Male / Female, %	37% / 63%	43% / 57%	39% / 61%
ECOG* 0 / 1, %	30% / 70%	7% / 93%	11% / 89%
Disease Stage IIIB / IV, %	7% / 93%	0 / 100%	4% / 96%
Brain Metastases*, %	17%	29%	39%
Non-smoker / Smoker / Former Smoker, %	77% / 3% / 20%	82% / 0 / 18%	75% / 4% /21%
Number of Prior Systemic Anti-cancer Therapy, Median, (Min, Max)	NA	1 (1, 4)	1 (1, 3)
Prior Treatment Type, % Chemotherapy / Immunotherapy EGFR Targeted Therapy[&]	 13% / 0 0	 96% / 39% 7%	 86% / 32% 14%

* Eastern Cooperative Oncology Group performance status scale

As of June 15, 2023, initial interim data was available from the 80 patients who have had measurable disease at baseline by blinded independent central review committee, had received at least two tumor assessments, had progressive disease or death, or discontinued from treatment. Of these 80 patients 28 are in the treatment-naïve patient group and 52 were previously treated, split evenly between the 160 mg and the 240 mg cohort. Safety data were available for all 86 patients. Based on these data, reduction in tumor size was observed across all cohorts. Confirmed ORRs (defined as a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression) were 79% among the treatment-naïve patients cohort, 46% among the previously treated 240 mg cohort and 39% in the previously treated 160 mg cohort. Median DOR was 15.2 months in treatment-naïve patients, 13.1 months in the 240 mg previously treated cohort and 9.7 months in the 160 mg previously treated cohort. Median PFS was 10.7 months in the treatment-naïve patients, 7.0 months in the 240 mg previously treated cohort and 5.7 months in the 160 mg previously treated cohort. The DCR, which includes complete responses, partial responses and stable disease, was 100%, 92% and 85% for each of these respective trial cohorts. These initial interim PFS and DOR data continue to mature with patients continuing in the clinical trial. Interim data from clinical trials may change as more patient data becomes available and are subject to audit

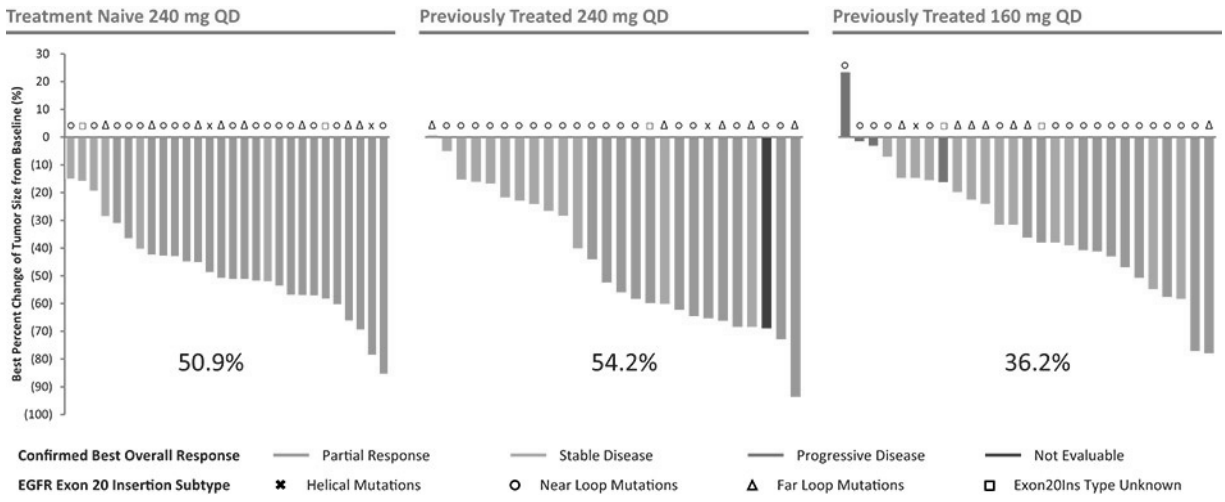
and verification procedures that could result in material changes in the final data. The following table describes these data.

	Treatment Naïve 240mg N=28	Previously Treated 240mg N= 26	Previously Treated 160mg N= 26
Confirmed ORR, % (95% CI)	78.6 (59.05, 91.70)	46.2 (26.59, 66.63)	38.5 (20.23, 59.43)
Best Response, n (%)			
Partial Response (PR)	22 (78.6)	12 (46.2)	10 (38.5)
Stable Disease (SD)	6 (21.4)	12 (46.2)	12 (46.2)
Progressive Disease (PD)	0	0	4 (15.4)
Not Evaluable	0	1 (3.8)	0
Not Performed	0	1 (3.8)	0
DoR, Median (Months) (95% CI)	15.2 (8.74, 24.84)	13.1 (5.62, 13.80)	9.7 (5.59, NA)
DCR (CR+PR+SD), % (95% CI)	100.0 (87.66, 100.00)	92.3 (74.87, 99.05)	84.6 (65.13, 95.64)
PFS, Median (Months) (95% CI)	10.7 (9.59, 24.84)	7.0 (5.45, 15.21)	5.7 (3.25, 8.28)

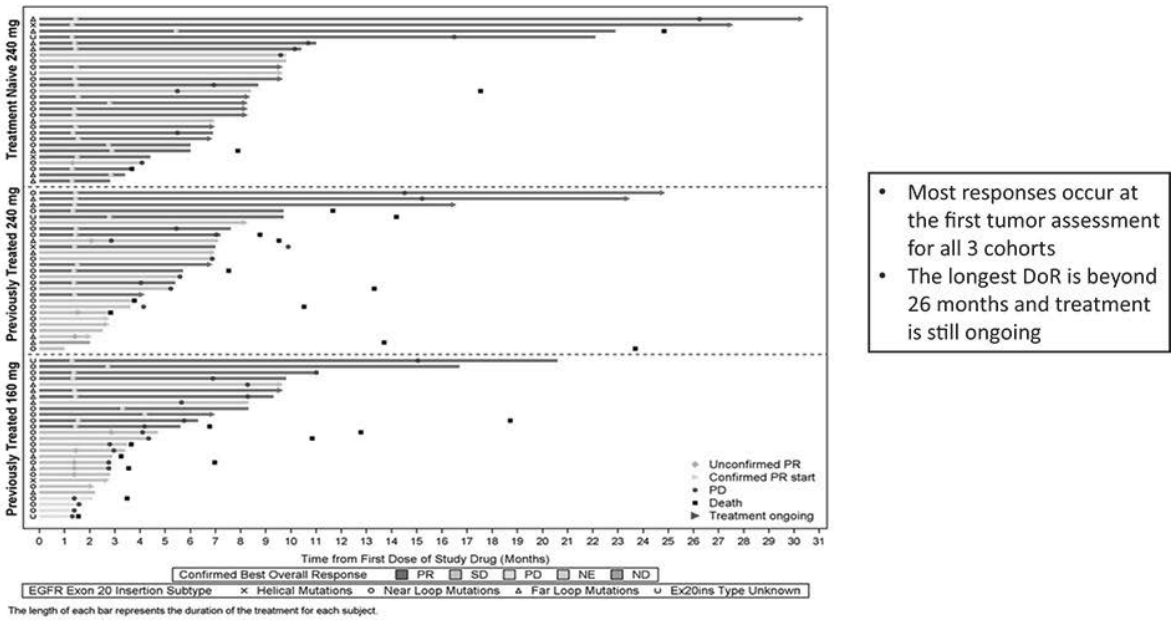
Interim data as of June 15, 2023. The ORR analysis is based on EGFR exon 20 patients who had measurable disease at baseline, had received at least two tumor assessments, had PD/death, or had discontinued treatment. Progression free survival analysis is based on EGFR exon 20 patients who had at least one tumor assessment, had PD/death, or had discontinued treatment.
ORR, objective response rate; DoR, duration of response; CI, confidence interval.

The extent of change in tumor size was evaluated across patients and shown in the figure below. Median tumor size reduction of 51% was observed in the treatment-naïve patients cohort, 54% was observed among pretreated patients in the 240 mg cohort and 36% in the pretreated 160 mg patient cohort. Patients on average achieved greater tumor size reduction in the 240 mg dose versus the 160 mg dose. Tumor size reduction was observed across the different locations of the exon 20 insertion (near loop, far loop and helical mutations).

Tumor size reduction was observed in all EGFR exon 20 insertion mutation subtypes with firmonertinib



Responses occurred rapidly with most patients having a partial response by the first tumor assessment at six weeks with responses ongoing in many patients as denoted in the figure below.



Firmonertinib was observed to be generally well tolerated and demonstrated safety results similar to prior firmonertinib trials. As of June 15, 2023, the following six (n=86) TRSAEs were observed: abnormal hepatic function (1), decreased platelet count (2), abnormal uterine bleeding (1), interstitial lung disease (1) and diarrhea (1). As of June 15, 2023, the following 21 (n=86) treatment-emergent serious adverse events (TESAEs) were observed: pleural effusion (6), pulmonary embolism (2), dyspnoea (1), interstitial lung diseases (1), decreased platelet count (2), increase lipase (1), pericardial effusion (3), pneumonia (3), cerebral infarction (1), abnormal uterine bleeding (1), depression (1), abnormal hepatic function (1), diarrhea (1), colon adenocarcinoma (1) and venous thrombosis (1). When AEs occurred, they were generally consistent with known class effects of EGFR TKIs. TRAEs of Grade 3 or higher deemed related to the study drug were noted in 13% among treatment-naïve patients, and 18% and 29% among previously treated patients dosed at the 160 mg and 240 mg daily level, respectively. TRAEs that led to dose interruption occurred in 14% of patients who received a 160 mg daily dose, 32% among previously treated patients who received a 240 mg daily dose and 23% among patients in the first-lint patient cohort. TRAEs that led to a reduction in dose occurred in 13% of untreated patients at the 240 mg dose and 11% and 18% among previously treated patients who received a 160 mg or 240 mg daily dose, respectively. The rate of trial discontinuation related to TRAEs was low, with only two trial patients

ending trial participation because of AEs across all treatment cohorts. The table below summarizes this safety and tolerability data as of June 15, 2023:

	240 mg QD (Treatment Naïve) N=30	240 mg QD (Pretreated) N =28	160 mg QD (Pretreated) N = 28
Overview of TRAEs (# of Patient, %)			
TRAE All Grade	29 (96.7%)	28 (100.0%)	25 (89.3%)
TRAE Grade ≥ 3	4 (13.3%)	8 (28.6%)	5 (17.9%)
Treatment-related SAE	1 (3.3%)	5 (17.9%)	0
TRAE Leading to Fatal Outcome	0	0	0
TRAE Leading to Dose Interruption	7 (23.3%)	9 (32.1%)	4 (14.3%)
TRAE Leading to Dose Reduction	4 (13.3%)	5 (17.9%)	3 (10.7%)
TRAE Leading to Treatment Discontinuation	0	1 (3.6%)	1 (3.6%)
Treatment Duration (Median)	8.4 mon	5.7 mo	4.0 mo
Relative Dose Intensity (%) (Mean, SD)	97.1 (8.0)	94.9 (13.5)	96.2 (9.4)

Data Cut: 15 Jun 2023

The most frequent TRAEs as of June 15, 2023 are detailed in the table below. The majority of these AEs were grade 1 or 2 and commonly associated with EGFR TKIs as a class.

	Treatment-naive 240 mg (N = 30)		Previously Treated 240 mg (N = 28)		Previously Treated 160 mg (N = 28)	
Preferred Term, Number of Patient(s) (%)	**Total**	**Grade ≥ 3**	**Total**	**Grade ≥ 3**	**Total**	**Grade ≥ 3**
Diarrhea	22 (73%)	0	24 (86%)	0	9 (32%)	2 (7%)
Anemia	13 (43%)	0	7 (25%)	1 (4%)	4 (14%)	1 (4%)
Aspartate Aminotransferase Increased	8 (27%)	0	7 (25%)	0	10 (36%)	0
Alanine Aminotransferase Increased	7 (23%)	0	7 (25%)	1 (4%)	8 (29%)	0
Blood Creatinine Increased	6 (20%)	0	8 (29%)	0	7 (25%)	0
Mouth Ulceration	9 (30%)	1 (3%)	4 (14%)	0	5 (18%)	0
Rash	7 (23%)	0	6 (21%)	0	4 (14%)	0
Electrocardiogram QT Prolonged	8 (27%)	1 (3%)	4 (14%)	2 (7%)	2 (7%)	0
White Blood Cell Count Decreased	6 (20%)	1 (3%)	5 (18%)	0	6 (21%)	0
Decreased Appetite	3 (10%)	0	8 (29%)	0	0	0
Weight Decreased	3 (10%)	0	7 (25%)	1 (4%)	3 (11%)	0
Skin Fissures	6 (20%)	0	3 (11%)	0	0	0
Paronychia	6 (20%)	0	2 (7%)	0	1 (4%)	0

Planned Adjuvant Study in NSCLC Patients with Uncommon EGFRm, including Exon 20 Insertion and PACC Mutations

We intend to participate in, or to conduct in parallel, a single multicenter, randomized, global pivotal Phase 3 clinical trial initiated in China to investigate the potential benefit of firmonertinib when administered to adult patients with Stage IIB to IIIB EGFRm NSCLC, after surgical resection. Eligibility in this clinical trial is restricted to patients with uncommon EGFR mutations including PACC, exon 20 insertion and other uncommon EGFRm. Participants are to be randomized on a 1:1 basis to receive either firmonertinib or placebo for three years and stratified based on stage of disease, mutation type and geographic origin. Participants are to receive firmonertinib daily over a three-year period with the primary endpoint to be disease free survival with secondary endpoints being OS and safety. We intend to participate in, or to conduct in parallel, this clinical trial in 2026, depending on the timing and results of the FURVENT study.

FURLONG — Completed Phase 3 Clinical Trial in Classical EGFRm First-Line NSCLC Patients

FURLONG was a 358-patient randomized, double-blinded, multi-center clinical trial with an active control arm, conducted in China by Allist, designed to compare the safety and efficacy of once daily dosing of 80 mg firmonertinib to 250 mg of gefitinib as first-line therapy in patients with locally advanced or metastatic NSCLC with classical EGFRm. Data from this trial supported the 2022 approval of firmonertinib in China for this patient population. The 358 patients enrolled in this Phase 3 trial were randomized on a 1:1 basis to receive either 80 mg of firmonertinib or 250 mg gefitinib orally as monotherapy in three-week cycles. All patients in the FURLONG clinical trial had either advanced Stage 3 or Stage 4 disease. Each cohort enrolled a similar number of women and non-smokers, and the distribution of classical mutation type was comparable, as was the number of patients with metastatic disease involving the central nervous system. The patient demographic information is illustrated below.

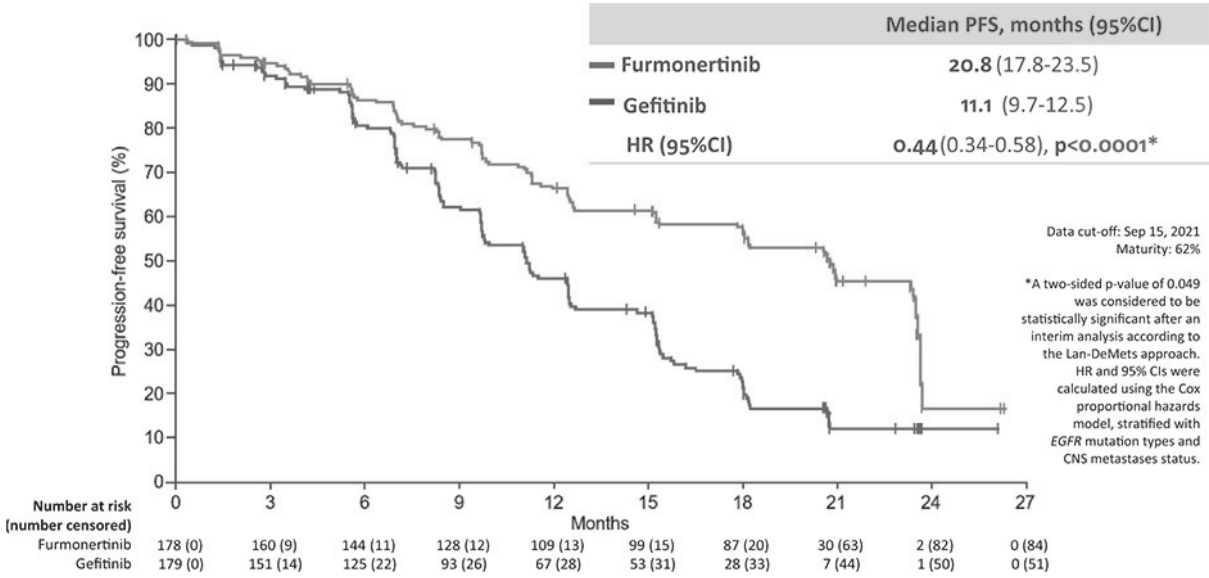
Characteristics, Data are Median (Range) or n (%)		Furmonertinib (n=178)	Gefitinib (n=179)
Age	Median	59 (31-81)	60 (32-83)
Sex	Female	116 (65%)	111 (62%)
	Male	62 (35%)	68 (38%)
ECOG PS*	0	39 (22%)	28 (16%)
	1	138 (76%)	151 (84%)
	2	1 (1%)	0
EGFR Mutation	Ex19Del	91 (51%)	92 (51%)
	L858R	87 (49%)	87 (49%)
Smoking History	Yes	41 (23%)	44 (25%)
	No	137 (77%)	135 (75%)
Disease Stage	III	10 (6%)	7 (4%)
	IV	168 (94%)	172 (96%)
CNS Metastases	Yes	63 (35%)	58 (32%)
	No	115 (65%)	121 (68%)

* Eastern Cooperative Oncology Group performance status scale

Firmonertinib demonstrated improved efficacy results as compared to gefitinib in the FURLONG clinical trial

Firmonertinib demonstrated clinically meaningful and statistically significant therapeutic benefit as compared to gefitinib in the FURLONG clinical trial. In this clinical trial, we saw patients with firmonertinib lived longer without progression of disease. Median PFS in the patient cohort that was treated with firmonertinib was 20.8 months as compared to 11.1 months for the cohort that received gefitinib, representing a hazard ratio of 0.443 with p value <0.0001. The ORR in the firmonertinib cohort, which included clinical trial participants exhibiting either a complete

response or a partial response to therapy, was 89% as compared to 84% in the gefitinib arm of the trial. The Kaplan-Meier curve of progression free survival in both cohorts is illustrated in the chart presented below.



Firmonertinib demonstrated improved safety results as compared to gefitinib in the FURLONG clinical trial

Firmonertinib also demonstrated favorable safety results as compared to gefitinib in the FURLONG clinical trial. Despite an extended median duration of exposure to firmonertinib of 18.3 months as compared to 11.2 months among patients in the gefitinib cohort, firmonertinib administration resulted in fewer Grade 3 TRAEs as compared to gefitinib, 11.2% versus 17.9%, and fewer treatment-related serious adverse events, 5.6% versus 6.1%. The following TRSAEs were observed in ten patients (n=178) in the FURLONG study: increased alanine aminotransferase (4), increased aspartate aminotransferase (3), cerebral infraction (2), abnormal hepatic function (1), decreased blood fibrinogen (1), decreased platelet count (1), diarrhea (1), cholecystitis (1), cholelithiasis (1), pancreatitis (1), gastroenteritis (1), and gastritis (1). The following TESAEs were observed in 44 patients (n=178) in the FURLONG study: pleural effusion (5), cerebral infarction (5), increased alanine aminotransferase (4), increased aspartate aminotransferase (3), pneumonia (3), dyspnoea (2), respiratory failure (2), pulmonary embolism (2), abnormal hepatic function (1), decreased blood fibrinogen (1), decreased platelet count (1), diarrhea (1), cholecystitis (1), cholelithiasis (1), pancreatitis (1), gastroenteritis (1), gastritis (1), and death (1). The rate of trial discontinuation related to TRAEs was 3.4%, with six trial patients ending trial participation because of AEs, one as a result of each of interstitial lung disease, hyperbilirubinemia, visual impairment, ECG QT prolongation, ALT/AST elevation and decreased platelet count.

Firmonertinib exhibited superior efficacy results in the treatment of CNS metastases in the FURLONG clinical trial

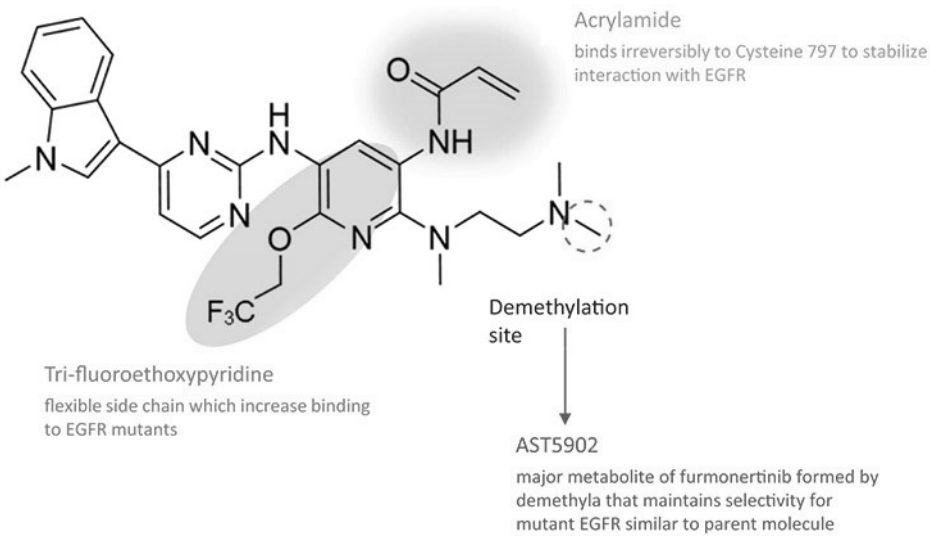
Of the 358 patients enrolled in FURLONG, 60 had measurable CNS lesions that could be evaluated. Among trial participants with measurable CNS metastases, firmonertinib produced a confirmed CNS metastases specific ORR of 91% vs. 65% for gefitinib. In the full analysis set of 133 patients who had measurable or non-measurable CNS metastases the median CNS metastases specific progression free survival was 20.8 months for firmonertinib versus 9.8 months for the cohort that received gefitinib. Additionally, in a post-hoc analysis of patients that did not present with CNS lesions at enrollment, none of the patients who were treated with firmonertinib developed new lesions related to CNS metastases during the trial period. Among gefitinib patients, 8 trial participants developed such lesions. We believe this difference reflects firmonertinib's enhanced potential to cross the blood-brain barrier which we believe may enable the prevention of CNS metastases.

Molecular Structure of Firmonertinib

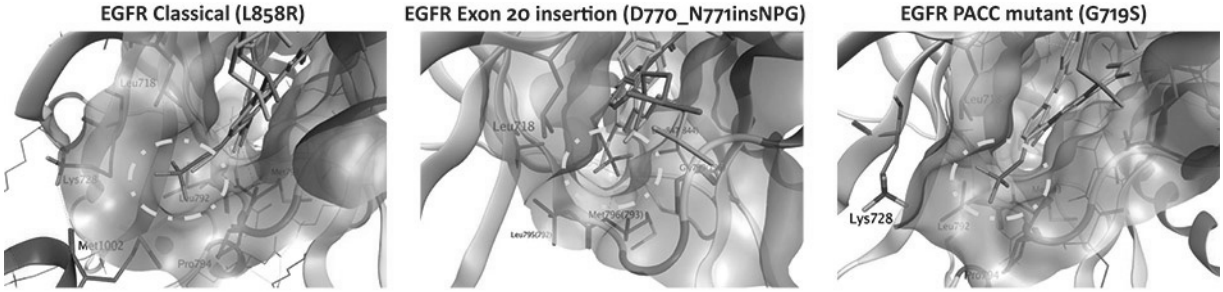
The molecular structure of firmonertinib is shown below. Firmonertinib contains an acrylamide side chain to confer irreversible binding to the EGFR kinase domain that may result in prolonged target inhibition and a flexible trifluoroethoxy side chain linked to a pyridine to provide additional contact points in the drug binding pocket, which we believe may enable improved binding across EGFR mutants as modeled below. It is believed that these two features of firmonertinib work together to enable broad inhibition of both classical and uncommon EGFR mutations such as exon 20 insertions and PACC mutations. In addition, the active metabolite of firmonertinib, AST5902 retained mutation specificity *in vitro*, which we believe may minimize toxicity due to EGFR inhibition in non-cancer cells.

The molecular structure of firmonertinib contains numerous advantageous features

The chemical structure of Firmonertinib



A trifluoroethoxy side chain was included to provide additional contact points across different EGFR mutant subtypes



A unique tri-fluoroethoxypyridine group provides additional contact points within the drug binding pocket of the kinase domain across EGFR mutants (yellow circle bottom panels) compared to osimertinib to improve binding

Our Antibody Drug Conjugate Collaborations

ADCs have emerged as an important therapeutic approach to delivering potent chemotherapy more directly to tumor cells which express a target on its cell surface while avoiding toxicity to normal cells which express the target at lower levels. However, currently available ADCs that utilize conventional antibodies that bind a single target as the drug delivery vehicle are still plagued by dose limiting and chronic toxicities. In addition, target expression tends to be heterogeneous within a tumor which can limit efficacy and/or restrict ADC use to only tumors that have high and mostly homogenous target expression.

Our Lepu Biopharma Antibody Drug Conjugate Collaboration

We also established an ADC collaboration with Lepu Biopharma in January 2025, to gain ex-Greater China, which includes mainland China, Hong Kong, Macau and Taiwan, rights to ARR-217, a CDH-17 targeted ADC, with the potential to treat gastrointestinal malignancies.

Our Aarvik Antibody Drug Conjugate Collaboration

To overcome the limitations of conventional ADCs we are advancing the development of next-generation ADCs through a research collaboration with Aarvik. Leveraging Aarvik's proprietary multi-target, multivalent antibody and site-specific conjugation platform, we have an ongoing research collaboration in an effort to develop an ADC that is potentially both safer and more effective than a conventional single target bivalent ADC. We identified a lead candidate (ARR-002) and initiated IND-enabling activities.

Our Alphamab Antibody Drug Conjugate Collaboration

In addition to our Aarvik ADC Collaboration, we established an ADC collaboration with Alphamab in June 2024. We are working with Alphamab to leverage their proprietary linker-payload platform and glycan-conjugation technology to identify novel ADCs for oncology indications globally, except greater China, which includes mainland China, Hong Kong, Macau and Taiwan where Alphamab retains the right to develop and commercialize ADCs.

Licenses, Partnerships and Collaborations

Allist Agreements

Global Technology Transfer and License Agreement

On June 30, 2021 (the Effective Date), we entered into a Global Technology Transfer and License Agreement with Allist, as amended on November 6, 2023 (the Allist License Agreement), pursuant to which (i) Allist granted to us an exclusive (even as to Allist and its affiliates), royalty-bearing, sublicensable license under certain intellectual property (including patents and know-how) owned or controlled by Allist to develop, manufacture and commercialize any product (the Licensed Product) containing firmonertinib or any of its salts or derivatives as an active ingredient (the Licensed Compound), for all uses (the Field), in all countries and territories (the Licensed Territory) other than greater China, which includes mainland China, Hong Kong, Macau and Taiwan (the Retained Territory); and (ii) we granted Allist a non-exclusive sublicensable license to use (1) any information, data and results that relate solely and exclusively to the Licensed Product and which we generate or collect in the conduct of clinical trials or preclinical activities in the Licensed Territory and (2) any improvements or enhancements that we make or discover under the License Agreement to the know-how licensed to us and is owned or controlled by us, to develop, manufacture, and commercialize the Licensed Compound and the Licensed Product for all uses in the Retained Territory.

The parties have appointed a joint collaboration committee, comprised of representatives from both us and Allist (the Collaboration Committee), to oversee the parties' development activities related to the Licensed Compound under the Allist License Agreement.

Under the terms of the Allist License Agreement, we are required to use commercially reasonable efforts to (i) develop the Licensed Product in the Licensed Territory, (ii) prepare and submit regulatory filings and seek regulatory approvals in all major market countries in the Licensed Territory and (iii) perform all commercialization activities for the Licensed Product in each country in the Licensed Territory in which the Licensed Product has received regulatory approval, and we are solely responsible for all the expenses associated with the foregoing (i)-(iii). We are also responsible for the manufacture and supply of the Licensed Product in the Licensed Territory, by ourselves or through a third-party manufacturer, for the purpose of conducting clinical trials, obtaining regulatory approval and commercializing the Licensed Product in the Licensed Territory.

In consideration of the licenses and rights granted to us under the Allist License Agreement, we granted to Allist a total of 1,276,250 shares of common stock for a purchase price of $0.0001 per share pursuant to that certain Subscription Agreement executed concurrently with the Allist License Agreement.

As additional consideration for the licenses and rights granted to us under the Allist License Agreement, we made an upfront, non-creditable and non-refundable cash payment of $40.0 million to Allist on the Effective Date (the Initial Payment). We are obligated to make development and regulatory approval milestone payments to Allist upon the achievement of specific milestone events related to the Licensed Product in an aggregate amount up to $110.0 million, of which we have paid $5.0 million upon meeting certain clinical milestones, and commercial milestone payments to Allist upon the achievement of specified net sales thresholds of the Licensed Product in an aggregate amount up to $655.0 million. We are also obligated to pay Allist tiered royalties ranging from high single digits to low mid-teens percentages on an incremental aggregated net sales basis on the net sales of any Licensed Products in the Licensed Territory made by or on behalf of us or our sublicensees. Our obligation to pay royalties for each Licensed Product begins from the date of the first commercial sale of such Licensed Product in a given country and extends until the latest of (i) the expiration of the last valid patent claim related to such Licensed Product's composition or approved indications in such country, (ii) the termination of any regulatory-based exclusivity period in such country, or (iii) ten years after the initial commercial sale of such Licensed Product in such country (the Allist License Royalty Term). Our obligation to make milestone payments also ceases upon the expiration of the Allist License Royalty Term on a product-by-product and country-by-country basis.

The Allist License Agreement will remain in force until the earlier occurrence of (i) the expiration of our obligation to pay royalties for all Licensed Products and (ii) the date that the Allist License Agreement is terminated pursuant to its early termination provisions (the Term). Either party has the right to terminate the Allist License Agreement, subject to specified cure periods, for the material breach by the other party or the bankruptcy or insolvency of the other party. In addition, we have the right to terminate the Allist License Agreement upon 60 days' prior written notice to Allist at any time, at our sole discretion, either in its entirety or on a Licensed Product-by-Licensed Product and country-by-country basis. Upon termination of the License Agreement, Allist will have certain specified reversion rights with respect to the Licensed Product if the termination is for any reason other than by us for the material breach by Allist, and if the termination is by us for the material breach by Allist, we would have the right to continue under the License Agreement in lieu of termination but with our milestone and royalty payment obligations being substantially reduced.

Joint Clinical Collaboration Agreement

On December 24, 2021, we entered into a Joint Clinical Collaboration Agreement (the Allist Collaboration Agreement) with Allist to govern the conduct of any global clinical trials to be conducted with the Licensed Products as specified in the Allist License Agreement (each, a Global Study). Pursuant to the Allist Collaboration Agreement, if either party or both parties wish to jointly conduct a Global Study, one or both parties (as the case may be) shall prepare and submit the proposed strategy, protocol design, budget, proposal for budget sharing and internal process timeline for such proposed Global Study to the Collaboration Committee that was appointed pursuant to the Allist License Agreement for its review at least 90 days in advance of the applicable protocol filing with the relevant regulatory authorities. Upon the approval by the collaboration committee of a development plan for the proposed Global Study that includes the allocation of the sponsorship for the conduct of the proposed Global Study and other details for conducting the proposed Global Study as specified in the Allist Collaboration Agreement, the proposed Global Study shall be deemed to be a "Joint Global Study" and such development plan a "Joint Global Development Plan." The parties have agreed in the Allist Collaboration Agreement that (i) we will be the sponsor of any Joint Global Study in the Licensed

Territory (as defined in the Allist License Agreement), (ii) Allist will be the sponsor of any Joint Global Study in the PRC (as defined in the Allist License Agreement) and (iii) the Collaboration Committee shall designate the party that will be the sponsor of any Joint Global Study in certain territories (Joint Territories). The parties will mutually agree on the global regulatory strategy for each Joint Global Study. The party that is the sponsor of a Joint Global Study will be responsible for (1) selecting the sites and investigators to be used in the conduct of the applicable Joint Global Study, and (2) developing strategies for, and preparing and submitting, all regulatory filings and applications for regulatory approval for the Licensed Products, in the sponsor's sponsored territory, except that Allist shall be responsible for developing strategies for, and preparing and submitting, all regulatory filings and applications for regulatory approval for the Licensed Products in the Joint Territories regardless of whether we are the sponsor in these territories. The parties will review the budget for each Joint Global Study and agree through the Collaboration Committee on the model to be used to share the expenses to be incurred in the conduct of such Joint Global Study.

Subject to applicable cure periods, the Allist Collaboration Agreement may be terminated by a party upon a material breach of the Allist Collaboration Agreement by the other party.

Aarvik Research Collaboration Agreement

On December 21, 2021, we entered into a Research Collaboration Agreement, as amended effective June 30, 2023 (the Aarvik Collaboration Agreement), with Aarvik, pursuant to which we and Aarvik agreed to collaborate on the discovery and characterization of novel ADCs with a goal to identify ADCs that may be suitable for further development by us in accordance with the applicable statements of work (each a SOW, collectively, the SOWs) until the completion of all activities in accordance with the applicable SOWs (collectively, the Aarvik Collaboration).

On August 9, 2024, we entered into an amendment and restatement of the Aarvik Collaboration Agreement (the Amended and Restated Aarvik Collaboration Agreement). Under the Amended and Restated Aarvik Collaboration Agreement, Aarvik granted us an exclusive option (the Option) to obtain exclusive rights to certain of Aarvik's intellectual property for the research, development, manufacture, use, commercialization, or other exploitation of the novel ADCs. Under the Amended and Restated Aarvik Collaboration Agreement, we are required to pay Aarvik a collaboration initiation fee and research fees as provided in the SOWs. We exercised the exclusive option simultaneously with entry into the Amended and Restated Aarvik Collaboration Agreement.

The parties have appointed a joint research committee, comprised of our representatives and representatives from Aarvik, to oversee the parties' research collaboration activities under the Amended and Restated Aarvik Collaboration Agreement. Aarvik has agreed, during the term of the Aarvik Collaboration and following our exercise of the Option, to certain exclusivity and ownership provisions with respect to ADCs.

Under the Amended and Restated Aarvik Collaboration Agreement, we are required to pay Aarvik a collaboration execution fee and research fees as provided in the SOWs. We further agreed to reimburse Aarvik for actual costs incurred in procuring other materials Aarvik will actually use in performing activities under the applicable SOWs. Because we have exercised the Option, we were required to make a one-time non-refundable option exercise payment of low single-digit millions and we will be obligated to make milestone payments to Aarvik upon the achievement of specific regulatory and sales milestone events related to the Aarvik Collaboration as specified and determined in the Amended and Restated Aarvik Collaboration Agreement. Combined regulatory milestone payments and sales milestone payments will not exceed $98.0 million per product. During the Aarvik Collaboration Royalty Term (as defined below), we are also obligated to pay Aarvik tiered royalties on aggregate net sales of products developed under the Aarvik Collaboration and commercialized by us or on our behalf at royalty rates in the mid-single digits, and we must also pay to Aarvik's upstream licensor a royalty of less than 1% on such net sales. Our obligation to pay royalties for each product, calculated on a product-by-product and jurisdiction-by-jurisdiction basis, begins from the date of the first commercial sale of each product within a given jurisdiction and extends until the earliest of (a) the first approval of a biosimilar product related to such product in such jurisdiction, which is made and sold by a different company, meeting specific government regulatory standards, (b) an anniversary of the date of the first commercial sale of such product in such jurisdiction, or (c) the expiration of the last valid claim of a patent included in the Collaboration IP that pertains to the any ADC generated within Aarvik Collaboration or any derivative thereof featured in such product within such jurisdiction (the Aarvik Collaboration Royalty Term).

The Amended and Restated Aarvik Collaboration Agreement will remain in full force and effect until the expiration of all Aarvik Collaboration Royalty Terms for all products under the Amended and Restated Aarvik Collaboration Agreement, unless terminated earlier. On a jurisdiction-by-jurisdiction and product-by-product basis, following the expiration of the Aarvik Collaboration Royalty Term, the license granted to us hereunder will become nonexclusive, perpetual, irrevocable, fully-paid and royalty-free. We can terminate the Amended and Restated Aarvik Collaboration Agreement for convenience. Either party can terminate the Amended and Restated Aarvik Collaboration Agreement for material breach that is not cured within a specified period, or for the other party's insolvency or certain bankruptcy events. Upon termination of the Amended and Restated Aarvik Collaboration Agreement with respect to the Target Pair or any given product, the licenses granted by Aarvik will terminate with respect to the applicable terminated Target Pair or product, and unless the Amended and Restated Aarvik Collaboration Agreement is terminated by us for Aarvik's uncured breach or insolvency, then the Collaboration IP will be assigned back to Aarvik. If the Amended and Restated Aarvik Collaboration Agreement is terminated only with respect to a particular jurisdiction (but not all jurisdictions) and a specific Target Pair or product, then we will grant to Aarvik an exclusive and fully paid-up right and license to use the licensed IP with respect to the terminated Target Pair or product in such jurisdiction.

InnoCare Clinical Collaboration Agreement

On June 23, 2023, we entered into a Clinical Collaboration Agreement (the InnoCare Collaboration Agreement) with InnoCare, pursuant to which we and InnoCare agreed to contribute resources to a clinical trial evaluating the use of firmonertinib in combination with InnoCare's ICP-189, a SHP2i (the InnoCare Collaboration Clinical Trial). Pursuant to the InnoCare Collaboration Agreement, we and InnoCare have mutually granted to each other a non-exclusive license to certain of the granting party's intellectual property solely for the purpose of conducting the InnoCare Collaboration Clinical Trial.

Under the InnoCare Collaboration Agreement, InnoCare has the right to use firmonertinib solely for the InnoCare Collaboration Clinical Trial. We and InnoCare have agreed that InnoCare is the regulatory sponsor for the InnoCare Collaboration Clinical Trial and has the sole right and responsibility to prepare all regulatory filings related to the InnoCare Collaboration Clinical Trial, including the protocol and IND filings, conduct the InnoCare Collaboration Clinical Trial, and communicate with regulatory authorities with respect to the InnoCare Collaboration Clinical Trial.

We maintain the right to review, comment on, and approve the protocol and IND related to the InnoCare Collaboration Clinical Trial and have the right to attend InnoCare's meetings with regulatory authorities regarding the InnoCare Collaboration Clinical Trial. InnoCare must also provide us with periodic updates regarding the InnoCare Collaboration Clinical Trial with respect to progress, safety and toxicity, and data and results.

Upon the completion of the InnoCare Collaboration Clinical Trial, InnoCare will lead the analysis of the results of the InnoCare Collaboration Clinical Trial and will provide us with the final report for the InnoCare Collaboration Clinical Trial for our comments. InnoCare has also agreed to provide us with any raw data generated from the InnoCare Collaboration Clinical Trial to the extent permissible by law. The final report and any raw data (collectively, the InnoCare Collaboration Report) from the InnoCare Collaboration Clinical Trial are jointly owned by us and InnoCare. We may not, without InnoCare's prior consent, use the InnoCare Collaboration Report for purposes of developing or commercializing ICP- 189 alone or in combination with firmonertinib. InnoCare may not, without our prior consent, use the InnoCare Collaboration Report for purposes of developing or commercializing firmonertinib alone or in combination with ICP-189.

Under the InnoCare Collaboration Agreement, we and InnoCare have agreed to equally share all incurred costs associated with the InnoCare Collaboration Clinical Trial in accordance with a mutually agreed upon budget and have agreed to provide each other with periodic expense reports detailing costs related to the InnoCare Collaboration Clinical Trial. As of December 31, 2025, we recognized approximately $0.9 million of research and development expenses related to incurred costs associated with the InnoCare Collaboration Clinical Trial. We and InnoCare have agreed to discuss such expense reports and determine the calculation of net amounts owed by one party to the other to ensure the appropriate equal sharing of costs associated with the InnoCare Collaboration Clinical Trial. If we or InnoCare become aware of any costs that may be in excess of the costs set out in the budget for the InnoCare Collaboration Clinical Trial, then the respective party shall notify the other party and we and InnoCare shall discuss such costs in order to determine

if such costs are permissible. InnoCare shall have the sole right to make the final decision on matters relating to the excess costs related to the InnoCare Collaboration Clinical Trial; however, we maintain the right to opt out of participating in the InnoCare Collaboration Clinical Trial if the costs surpass a certain threshold above the budget, provided that we will not have rights to the InnoCare Collaboration Report.

The InnoCare Collaboration Agreement will remain in full force and effect until the delivery of the InnoCare Collaboration Report, unless terminated earlier. The InnoCare Collaboration Agreement may be terminated for material breach upon written notice with a period to cure such material breach. The InnoCare Collaboration Agreement may also be terminated immediately by either party if either one believes that there is a material safety issue in the conduct of the InnoCare Collaboration Clinical Trial that cannot be resolved by a protocol amendment satisfactory to both parties after discussion thereof.

Alphamab Collaboration

On June 4, 2024, we entered into a Research and Collaboration Agreement with Alphamab, a wholly owned subsidiary of Alphamab Oncology, pursuant to which the Company and Alphamab will discover, develop and commercialize novel antibody drug conjugates for the treatment of cancers (the Alphamab Agreement).

Under the Alphamab Agreement, and subject to our payment to Alphamab of the applicable research costs, Alphamab will grant us an exclusive, royalty-bearing, sublicensable license under certain Alphamab intellectual property and joint intellectual property to develop and commercialize such products in all fields of use worldwide, except greater China, which includes mainland China, Hong Kong, Macau and Taiwan (the Retained Territory). Alphamab retains the right to develop and commercialize such products in the Retained Territory. Under the Alphamab Agreement, we granted to Alphamab a royalty-free, perpetual license, which is exclusive during the term of the Alphamab Agreement and non-exclusive thereafter, under all intellectual property rights conceived, discovered, developed or otherwise made solely by us or jointly with Alphamab pursuant to the activities under the Alphamab Agreement for any and all purposes within the Retained Territory. Upon commencement of activities to manufacture the products for use in certain clinical trials, Alphamab will grant us a royalty-bearing license under certain Alphamab intellectual property to manufacture the applicable products. Under the Alphamab Agreement, Alphamab is entitled to an upfront payment and potential development and sales milestone payments of up to an aggregate of $615.5 million from us. Additionally, Alphamab is entitled to receive royalties in the low- to mid- single digit percent range on net sales of products outside greater China that may arise from the Alphamab Agreement.

The Alphamab Agreement is subject to termination (i) by either party for customary purposes, including the material breach by or bankruptcy of the other party, (ii) by us for convenience, (iii) by Alphamab due to our challenge of certain patents held by Alphamab, or (iv) by Alphamab on a product-by-product basis due to our failure to carry out certain diligence obligations or in certain instances if there is a change of control of the Company.

Lepu Biopharma Agreement

On January 21, 2025, we entered into the Lepu Biopharma License Agreement with Lepu Biopharma, pursuant to which Lepu Biopharma granted us a right to develop and commercialize ARR-217 (MRG007), an antibody drug conjugate for gastrointestinal cancers, outside greater China, which is mainland China, Hong Kong, Macau and Taiwan.

Under the Lepu Biopharma Agreement, Lepu Biopharma granted to us: (i) an exclusive, royalty-bearing, sublicensable license under certain intellectual property owned or controlled by Lepu Biopharma, to develop, manufacture and commercialize any product containing ARR-217 for all uses in all countries and territories other than Greater China, which is mainland China, Hong Kong, Macau and Taiwan (the ArriVent Territory); and (ii) a non-exclusive license under certain intellectual property controlled by Lepu Biopharma to develop, manufacture and commercialize any product containing ARR-217 for use in oncology in the ArriVent Territory. Under the Lepu Biopharma Agreement, Lepu Biopharma is entitled to receive a one-time upfront payment and near-term milestone payments totaling $47.0 million in cash and is eligible to receive up to $1.16 billion in development, regulatory and sales milestones and tiered royalties in high single-digit to low-teen percentages on net sales in the ArriVent Territory.

The Lepu Biopharma Agreement is subject to termination: (i) by either party, subject to specified cure periods, for the material breach by the other party or the bankruptcy or insolvency of the other party, (ii) by us for convenience, subject to a specified notice period, (iii) by Lepu Biopharma due to our challenge of certain patents controlled by Lepu Biopharma, or (iv) by Lepu Biopharma due to our failure to carry out certain diligence obligations.

Manufacturing

We oversee and manage third party CMOs to support development and manufacture of product candidates for our clinical trials, and, if we receive marketing approval, we will rely on such manufacturers to meet commercial demand. We expect this strategy will enable us to maintain a more efficient infrastructure, avoiding dependence on our own manufacturing facility and equipment, while simultaneously enabling us to focus our expertise on the clinical development and future commercialization of our products.

Currently, we rely on, and have agreements with, two third-party contract manufacturers, Zhejiang Raybow Pharmaceutical Company., Ltd. (Raybow) and SynTheAll Pharmaceutical Co., Ltd. (WuXi STA) to supply the drug substance for firmonertinib to be used in on-going and planned clinical trials and with WuXi STA, with whom we have executed technology transfer related to the manufacture of drug product, to manufacture the clinical trial and initial commercial launch supplies of firmonertinib drug product. Both of our third-party contract manufacturers are located in China, but WuXi STA has manufacturing capabilities globally, including in the United States and Europe. We expect to enter into commercial supply agreements with WuXi STA for both drug substance and drug product prior to any potential approval of firmonertinib. We expect to rely on manufacturers in China for ARR-217 drug substance and drug product for use in initial clinical studies and also expect to rely on WuXi XDC Cayman, Inc., (WuXi XDC) for the manufacture of ARR-002 drug product and drug substances for initial clinical studies.

Firmonertinib drug product is manufactured via conventional pharmaceutical processing procedures, employing commercially available excipients and packaging materials. The procedure and equipment employed for manufacture and analysis are consistent with standard organic synthesis or pharmaceutical production, and are transferable to a range of manufacturing facilities, if needed. We intend to also maintain the current drug substance manufacturer as part of our supply chain strategy.

The National Defense Authorization Act for Fiscal Year 2026, enacted in December 2025, included a section titled "Prohibition on Contracting with Certain Biotechnology Providers," aimed at discouraging federal contracting with certain biotechnology companies for biotechnology equipment or services in China and other countries of concern, also known as the BIOSECURE Act. The statute prohibits federal executive agencies from procuring any biotechnology equipment or service from a biotechnology company of concern or contracting with any such company or any entity that procures or uses equipment or services from a biotechnology company of concern. Such prohibitions may limit our ability to obtain federal government grants for research involving our products, if approved, or product candidates manufactured in China or to enter contracts to sell any such products, if approved, to the federal government. Accordingly, we are taking measures to strengthen our supply chain in the event that Raybow, WuXi STA, or one of our other manufacturers is impacted. We intend to identify alternative potential manufacturers to ensure we have a sufficient stockpile of drug substance and drug product in the United States. We will also continue to closely monitor geopolitical risk and implement additional mitigations and supply chain redundancies, as needed. See the risk factor entitled "We currently rely on a Chinese third party for the manufacture of firmonertinib and ARR-217, for clinical development, and future supply of firmonertinib, and expect to continue to rely on third parties for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of firmonertinib or ARR-217 or such quantities at an acceptable cost, which could delay, prevent or impair our development or potential commercialization efforts."

Competition

The biotechnology and pharmaceutical industries have made substantial investments in recent years into the rapid development of novel treatments for NSCLC.

We face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research

institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, technologies and data emerge within the field of oncology and, furthermore, within the treatment of NSCLC.

In addition to the current standard of care treatments for patients with NSCLC, numerous commercial and academic preclinical studies and clinical trials are being undertaken by a large number of parties to assess novel technologies and product candidates.

Companies that compete with us directly on the level of commercialization or development of product candidates targeting EGFR mutation-positive NSCLC include, but are not limited to, AstraZeneca, Johnson & Johnson, Blossom Hill Therapeutics, Dizal Pharmaceutical, Oric Pharmaceuticals, Black Diamond Therapeutics, Inc., Cullinan Therapeutics, Inc., Taiho Pharmaceutical Co., Ltd., Boehringer Ingelheim and Bayer AG.

Many of our competitors, either alone or in combination with their respective strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, the regulatory approval process and marketing than we do. Mergers and acquisition activity in the pharmaceutical, biopharmaceutical and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These competitors also compete with us in recruiting and retain qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if one or more of our competitors develop and commercialize products that are safer, more effective, better tolerated, or of greater convenience or economic benefit than our proposed product offering. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be product safety, efficacy, convenience and treatment cost.

Intellectual Property

Intellectual property is of vital importance in our field and in biopharmaceuticals 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.

Firmonertinib

Through our licensor Allist, we have sought and obtained patent protection in the United States and internationally related to firmonertinib. For firmonertinib and our future product candidates our strategy is to pursue patent protection covering compositions of matter and methods of use. In addition, we seek to identify additional means of obtaining patent protection including formulation and dosing regimen-related claims, as well as manufacturing-related claims, which may enhance our commercial success. We may 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. As of December 31, 2025, our intellectual property portfolio for firmonertinib includes issued patents and pending patent applications in the U.S. and internationally.

With regard to the firmonertinib molecule itself, we exclusively license from Allist two issued patents in the US, and one issued patent in each of, Canada, Europe, Japan and South Korea. These patents are expected to expire as

indicated in the table below (composition of matter). The U.S. patents are reissue patents covering firmonertinib, other compounds represented by a general formula, and pharmaceutically acceptable salts of such compounds. The patents also cover related pharmaceutical compositions, methods for treating an EGFR activating or resistant mutation mediated lung cancer and methods for selectively inhibiting an EGFR activating or resistant mutation over a wild-type EGFR to a lung cancer patient.

With regard to mesylate salts of firmonertinib, we exclusively license from Allist one issued patent in each of the United States, Canada, Europe, Japan and South Korea. The U.S. patent covers mesylate salts of firmonertinib, as well as pharmaceutical compositions, methods for preparing such mesylate salts and methods for treating a patient suffering from cancers. With regard to crystalline forms, we also exclusively license from Allist one issued patent in each of the United States, Canada, Europe, Japan and South Korea. The U.S. patent covers two crystalline forms of mesylate salts of firmonertinib, as well as pharmaceutical compositions, methods for preparing such crystalline forms, and methods for treating a patient suffering from cancers. Collectively, these patents are expected to expire as indicated in the table below (composition of matter).

With regards to methods of manufacturing firmonertinib, we exclusively license from Allist two pending patent applications in each of the United States and Europe. These applications, if issued, would expire as indicated in the table below (composition of matter).

With regard to methods of use for firmonertinib, we exclusively license from Allist three families of national stage patent applications pending in multiple countries, including United States, Canada, Europe, Japan and South Korea. The national stage patent application families relate to use of firmonertinib to treat disease, such as NSCLC, in patients (a) having exon 20 insertion mutations or (b) having an HER2 exon 20 insertion mutation and/or EGFR rare mutation and (c) use of firmonertinib to treat disease, such as NSCLC, in patients having EGFR PACC mutations, , as well as pharmaceutical compositions containing therapeutically effective amounts of firmonertinib.. Any U.S. or foreign patents issued from the national stage applications are expected to expire as indicated in the table below (composition of matter).

ARR-217

Lepu Biopharma has exclusively licensed us two PCT applications relating to antibodies and ADCs, including ARR-217. Any U.S. or foreign patents issued from such PCT applications are expected to expire as indicated in the table below (composition of matter).

ARR-002

Aarvik has exclusively licensed us one PCT application relating to antibody scaffolds and ADCs comprising such scaffolds and one PCT application relating to antibody scaffolds and ADCs comprising such scaffolds, including ARR-002. Any U.S. or foreign patents issued from national stage filings of the PCT patent applications, are expected to expire as indicated in the table below (composition of matter).

ARR-421

We are joint owners with Alphamab of a provisional application relating to the ARR-421 program and Alphamab has exclusively licensed us a PCT application relating to camptothecin derivatives and conjugates comprising the same. Any U.S. or foreign patents issued from such applications are expected to expire as indicated in the table below (composition of matter).

We may file additional patent applications in support of current and new product candidates as well as new platform and core technologies.

Patent Expiration Dates* of Product Candidates Patents/Applications by Category

Product Candidate	Composition of Matter	Methods of Treatment	Manufacturing
Firmonertinib	2035, 2037	2042-2043	2042
ARR-217	2044, 2045		
ARR-002	2044, 2045		
ARR-421	2045, 2047		

*Expiration dates of granted patents assume payment of all appropriate maintenance, renewal, annuity or other governmental fees. Expiration dates of pending patent applications assume grant of the patent applications. The expiration dates in this table do not take into account potential patent term extensions or adjustments. Actual expiration dates may vary based on interpretations of laws in the jurisdictions in which patents have granted.

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 any such 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 product candidates will depend 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."

The terms of individual patents depend upon the legal term of the patents in the countries in which they are obtained. In most jurisdictions, 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 (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 term of a patent that covers an FDA-approved drug may also be eligible for 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 subject drug candidate 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 to extend the term of a patent that covers an approved drug are available in Europe and other foreign jurisdictions. 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 that such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see "Risk Factors — Risks Related to Our Intellectual Property."

In some instances, we may submit patent applications directly to the USPTO as provisional patent applications. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

U.S. non-provisional applications and PCT applications may claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of

the original priority date of the patent application, and to designate all of the PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Office. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We seek to file patent applications containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to pursue maximum coverage and value for our processes and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. 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. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions. For more information regarding the risks related to our intellectual property, see "Risk Factors — Risks Related to Our Intellectual Property."

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. Third-party patents could require us to alter our development or commercial strategies, or our products or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material

adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, see "Risk Factors — Risks Related to Our Intellectual Property."

When available to expand market exclusivity, our strategy is to obtain, or license additional intellectual property related to current or contemplated development platforms, core elements of technology and/or clinical candidates.

Government Regulation

Regulation Within the United States

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

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act (FDC Act) and its implementing regulations and while biological products are regulated under the FDC Act, the Public Health Service Act (PHS Act), and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions brought by the FDA and the Department of Justice (DOJ) or other governmental entities. Such sanctions could include, but are not limited to, FDA refusal to approve pending marketing applications, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

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

Once a pharmaceutical or biological candidate is identified for development, it enters the preclinical or nonclinical testing stage. Nonclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as potentially animal studies to assess the characteristics and potential safety and activity of the product. The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, amended both the FDC Act and the PHS Act to specify that nonclinical testing for drugs may, but is no longer required to, include *in vivo* animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by competing various *in vitro* assays (e.g., cell-based assays, organ chips, or microphysiological systems), *in silico* studies (i.e., computer modeling), other human or non-human biology-based tests (e.g., bioprinting), or *in vivo* animal tests.

The results of nonclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, analytical data and a proposed clinical trial 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. Long-term nonclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not otherwise notified the sponsor of the IND within this 30-day period, then the clinical trial proposed in

the IND may begin, unless the FDA, within the 30-day time period, imposes 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 the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of one or more qualified investigators. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice (GCP) (an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors), which includes, among other things, the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial; as well as (iii) under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. 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.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an independent institutional review board (IRB) or ethics committee for approval at each clinical site before each trial may be initiated, and the IRB must monitor the study until completed and otherwise comply with IRB regulations. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB may also require the clinical trial at the site to be halted, either temporarily or permanently (or impose other conditions), for failure to comply with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries, including clinicaltrials.gov.

Clinical trials to support new drug applications (NDAs) or biologics license applications (BLAs) for marketing approval of pharmaceutical or biological products, respectively, are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase 1, the initial introduction of the product candidate into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population with a specified disease or condition to preliminarily evaluate the effectiveness of the product candidate for a particular indication, determine dosage tolerance and optimum dosage, and to identify possible adverse effects and safety risks. If a product candidate demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to further evaluate dosage, obtain substantial evidence of clinical efficacy and further test for safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the product candidate and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled clinical trials to demonstrate the efficacy of the therapeutic product candidate. Results from a single adequate and well-controlled trial may be sufficient in certain instances, such as: (i) where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible; or (ii) when submitted in conjunction with other confirmatory evidence.

Moreover, post-approval trials, sometimes referred to as "Phase 4" clinical 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

Congress also recently amended the FDC Act to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug or biologic to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Sponsors must submit a diversity action plan to the FDA by the time the sponsor submits the relevant clinical trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. If the FDA objects to a sponsor's diversity action plan or otherwise requires significant changes to be made, it could delay initiation of the relevant clinical trial.

Concurrent with clinical trials, companies usually complete nonclinical animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with current good manufacturing practices (cGMPs). The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. For biologics in particular, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined in order to help reduce the risk of the introduction of adventitious agents. 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.

Assuming successful completion of the required clinical testing, an NDA/BLA is prepared and submitted to the FDA. FDA approval of the NDA/BLA is required before marketing of the product may begin in the U.S. The NDA/BLA must include the results of all product development, nonclinical, clinical and other testing, a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls, along with proposed labeling and other relevant information. The cost of preparing and submitting an NDA/BLA is substantial. The submission of most prescription drug marketing applications is additionally subject to a substantial application user fee, and the applicant under an approved NDA/BLA is also subject to an annual program fee for each prescription product. These fees are typically increased annually. A waiver of such fees may be obtained under certain limited circumstances.

Congress is required to re-authorize the agency's user fee programs every five years, and current legislative provisions supporting the prescription drug-specific program are set to expire on September 30, 2027. The FDA has 60 days from its receipt of an NDA/BLA to determine whether the application will be filed based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA/BLA for filing, in which case the FDA may issue a Refuse to File letter. In this event, the NDA/BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. If the submission is filed, the FDA begins an in-depth review to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act (PDUFA) guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity, or an original BLA, to review and act on the submission. This review typically takes twelve months from the date the NDA/BLA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted. Most applications designated for priority review products are reviewed in six months of the date of the FDA's filing determination. Priority review can be applied to NDAs or BLAs for products that are designed to treat a serious condition, where the FDA determines the product may offer significant improvements in safety or effectiveness or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA on one occasion for three additional months to consider a "major amendment," which may include certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug/biologic products, or drug/biologic products that present difficult questions of safety or efficacy, to an independent advisory committee — typically a panel that includes clinicians and other scientific experts — for review, evaluation and a recommendation as to whether the application

should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA/BLANDA/BLA, the FDA may inspect one or more clinical sites to assure that the trials support the application were conducted compliance with GCP. Additionally, the FDA will typically inspect the facility or the facilities at which the product is manufactured to assess compliance with cGMPs, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity and, for a biologic, its potency. The FDA will not approve the product unless compliance with cGMP, is satisfactory and the NDA/BLA contains data that provide substantial evidence that the product is safe and effective in the indication sought.

After the FDA evaluates the NDA/BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter (CRL). 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 submission and may require additional clinical data, such as an additional clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing, in order for the FDA to reconsider the application. In September 2025, the FDA began publishing CRLs soon after issuing them to the respective sponsors, breaking with long standing agency tradition of publishing CRLs with approval documentation after the product is approved. If a CRL is issued, the sponsor must resubmit the NDA/BLA, 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/BLA does not satisfy the criteria for approval. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

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. As a condition of NDA/BLA approval, the FDA may also require a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks. If the FDA concludes a REMS is needed, the sponsor of the marketing application must submit a proposed REMS. The FDA will not approve the NDA/BLA without an approved REMS, if required. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are later identified.

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

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products, including prescription drugs and biologics, are required to register and disclose certain clinical trial information on a public registry maintained by the U.S. National Institutes of Health (NIH). Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to report the results of their clinical trials after completion, although such results disclosure can be delayed in certain circumstances for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government.

Pediatric Information

Under the Pediatric Research Equity Act (PREA) sponsors must 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 BLAs, as well as certain supplements to approved NDAs and BLAs, must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. FDA may grant full or partial waivers, or deferrals, for submission of data. 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. With certain exceptions, PREA does not apply to any drug for an indication for which orphan designation has been granted.

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

Congress periodically considers enacting new incentives or mandates applicable to pediatric drug development, and the regulatory requirements applicable to pediatric drug developers may change in the future. For example, in February 2026, bipartisan legislation was signed into law and will grant FDA authority to assess penalties against companies that do not complete required pediatric studies.

Expedited Development and Review Programs & Accelerated Approval Pathway

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational drug or biologic. 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 products 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/BLA 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 marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA/BLA.

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/BLA 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 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 or original BLAs under its current PDUFA review goals.

In 2025, the FDA created a new voucher program called the Commissioner's National Priority Voucher (CNPV), with the goal of radically expediting therapeutic product review and approval processes. The agency may award a CNPV to a company or a specific product candidate that demonstrates alignment with certain national health priorities. The FDA aims to take action on a marketing application for which a CNPV is used within one to two months after the filing date.

In addition, a product candidate may be eligible for accelerated approval. Drugs or biologics 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 product 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. Product 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.

None of these FDA programs change the standards for approval but they 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

Once an NDA/BLA is approved, a product will be 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. For instance, the FDA closely regulates the post-approval marketing, labeling, advertising and promotion of drugs, including through its enforcement of standards and regulations for direct-to-consumer advertising, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. 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 the company 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 manufacturers' communications on the subject of off-label use of their products. Companies may share truthful and not misleading information that is not inconsistent with the labeling, and the FDA recently published guidance for industry that outlines modernized recommendations for how drug manufacturers can share truthful, scientifically sound, and clinically relevant information on unapproved uses with health care providers in a non-promotional way.

Moreover, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or an NDA/BLA supplement, which may require the applicant to develop additional data or conduct additional nonclinical studies and clinical trials. In particular, securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled clinical trials to demonstrate the product's safety and efficacy in the new indication. Even if such trials are conducted, the FDA may not approve any expansion of the labeled indications for use in a timely fashion, or at all.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA/BLA. The FDA also may require post-marketing testing, known as Phase 4 testing (to gain additional experience from the treatment of patients in the intended therapeutic indication), REMS or surveillance to monitor the effects of an approved product, or FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacturing, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA and certain state agencies to assess compliance with cGMPs and other laws and regulations. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs.

FDA regulations also require, among other things, the investigation and correction of any deviations from cGMP and the imposition of reporting and documentation requirements upon the NDA/BLA sponsor and any third-party manufacturers involved in producing the approved therapeutic product. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards or if it encounters problems following initial marketing.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of requirements for post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on ongoing or planned clinical 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 distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (PDMA), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The Drug Supply Chain Security Act (DSCSA) was enacted in 2013 with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandated resource-intensive obligations for manufacturers, wholesale distributors and dispensers over a 10-year period that culminated in November 2023. Most recently, the FDA announced a one-year stabilization period to November 2024 followed by trading partner-specific exemptions through specified dates in 2025, giving entities subject to the DSCSA additional time to finalize interoperable tracking systems and to ensure supply chain continuity. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict

whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation to a drug intended to treat a rare disease or condition, which is defined as one affecting fewer than 200,000 individuals in the United States or more than 200,000 individuals where there is no reasonable expectation that the product development cost will be recovered from product sales in the United States. Orphan Drug Designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the drug and its potential orphan use will be disclosed publicly by the FDA; the posting will also indicate whether a drug is no longer designated as an orphan drug. More than one product candidate may receive an Orphan Drug Designation for the same indication. Orphan Drug Designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Under PREA, submission of a pediatric assessment is not required for pediatric investigation of a product that has been granted Orphan Drug Designation. However, in 2017, the scope of PREA was extended to require pediatric studies for products intended for the treatment of an adult cancer that are directed at a molecular target and that are determined to be substantially relevant to the growth or progression of a pediatric cancer. In addition, the FDA finalized guidance in 2018 indicating that it does not expect to grant any additional Orphan Drug Designation to products for pediatric subpopulations of common diseases. Nevertheless, the FDA intends to still grant Orphan Drug Designation to a drug or biologic that otherwise meets all other criteria for designation when it prevents, diagnoses or treats either (i) a rare disease that includes a rare pediatric subpopulation, (ii) a pediatric subpopulation that constitutes a valid orphan subset, or (iii) a rare disease that is in fact a different disease in the pediatric population as compared to the adult population.

If an orphan drug-designated product subsequently receives FDA approval for the disease for which it was designed, the product will be entitled to seven years of product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances (such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues), for seven years. Orphan exclusivity does not block the approval of a different drug or biologic for the same rare disease or condition, nor does it block the approval of the same drug or biologic for different conditions. If a competitor obtains approval of the same drug, as defined by the FDA, or if our product candidate is determined to be the same drug as a competitor's product for the same indication or disease, the competitor's exclusivity could block the approval of our product candidate in the designated orphan indication for seven years, unless our product is demonstrated to be clinically superior to the competitor's drug. A product with Orphan Drug Designation may not receive orphan exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

FDA Regulation of Companion Diagnostics

Certain of our product candidates may require an in vitro diagnostic to identify appropriate patient populations for investigation and/or use of our product candidates. These diagnostics, often referred to as companion diagnostics, are regulated as medical devices. In the United States, the FDC Act and its implementing regulations, and other federal and state statutes and regulations, govern, among other things, medical device design and development, nonclinical 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, 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 (PMA). Most companion diagnostics for oncology product candidates utilize the PMA pathway.

If use of companion diagnostic is deemed essential to the safe and effective use of a drug or biological 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 product candidates, a companion diagnostic device and its corresponding drug 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 drug 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 may be considered a significant risk device under the FDA's Investigational Device Exemption (IDE) regulations. In which case, the sponsor of the diagnostic device will be required to submit and obtain approval of an IDE application, and subsequently comply with the IDE regulations. However, 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 applicable IDE regulations and the IND regulations. The guidance provides that, depending on the details of the study plan and degree of risk posed to subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE.

The FDA has generally required companion diagnostics intended to select the patients who will respond to cancer treatment to obtain approval of a PMA for that diagnostic simultaneously with approval of the therapeutic. 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. In addition, 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. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality Management System Regulation (QMSR), which imposes elaborate testing, control, documentation and other quality assurance requirements. The QSR was developed and implemented to harmonize the FDA's previous medical device current good manufacturing practice regulations (referred to as the Quality System Regulation, or QSR) with the International Organization for Standardization standard for device quality management systems (ISO 13485:2016) and it became effective on February 2, 2026.

If the FDA's evaluation of the PMA application is favorable, the FDA may issue an approvable letter requiring the applicant's agreement to specific conditions, 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's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. 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. If and when 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. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards are not maintained, or problems are identified following initial marketing.

In November 2025, the FDA issued a proposed rule to reclassify certain nucleic acid-based test systems indicated for use with a corresponding approved oncology therapeutic product from Class III (PMA) into Class II, subject to 510(k) premarket notification with special controls. This change, if finalized in 2026, will decrease the regulatory burden on industry because manufacturers of these kinds of in vitro diagnostic products will no longer have to submit a PMA and receive FDA approval before marketing the test.

After a device is commercialized, 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 and comparable state agencies. The FDA also may inspect foreign facilities that export products to the United States.

The Hatch-Waxman Amendments & Marketing Exclusivity for Small Molecule Drug Products

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. 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, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors as part of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, nonclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug pursuant to each state's laws on drug substitution.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or "carves out") any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA 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. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Regulatory exclusivity provisions under the FDC Act can delay the submission or the approval of certain marketing applications for small-molecule drug products. Upon NDA approval of a new chemical entity (NCE), which is a drug that contains no active moiety (which is the molecule or ion responsible for the action of the drug substance) that has been approved by FDA in any other NDA, that NDA receives five years of non-patent data and marketing exclusivity within the United States during which FDA cannot accept for review any (i) ANDA seeking approval of a generic version of that drug, or (ii) any NDA submitted under Section 505(b)(2) (505(b)(2) NDA) of the Act (also referred to as a 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. An application referencing the protected NDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed, i.e., certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no application may be filed before the expiration of the five-year exclusivity period.

Certain changes to a drug, such as the addition of a new indication to the package insert, or new dosages or strengths of an existing drug, can be the subject of a three-year non-patent period of data exclusivity if the NDA (or supplement to an existing NDA) contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the applicant that are deemed by the FDA to be essential to the approval of the application. 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 that is does not reference data in another drug's approved application. However, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to, all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Reference Product Exclusivity for Biological Products

In March 2010, the Patient Protection and Affordable Care Act was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009 (BPCIA). The BPCIA amended the PHS Act to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. This amendment to the PHS Act, in part, attempts to minimize duplicative testing. We expect that our ADC product candidates are regulated as biological products that will be submitted for approval pursuant to a BLA and will be subject to the BPCIA.

Since that time, the FDA has approved more than 80 biosimilars, including the first interchangeable biosimilars in 2021. The FDA has also issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biosimilars. It has also created a public database that contains information on all FDA-licensed biological products, including biosimilars, called the Purple Book.

Biosimilarity requires that the follow-on biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the follow-on product and the reference product in terms of safety, purity and potency. The biosimilar applicant must demonstrate that its product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) toxicity assessments; and (3) for some biological products, one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

A reference biological product is granted twelve years of data exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed. As part of the Consolidated Appropriations Act for 2023, Congress amended the PHS Act in order to permit multiple interchangeable products approved on the same day to receive and benefit from this one-year exclusivity period. If pediatric studies are performed and accepted by the FDA as responsive to a written request from FDA, as described above, the 12-year exclusivity period will be extended for an additional six months. In

addition, the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, policy proposals have sought to reduce the 12-year reference product exclusivity period and, more recently, to potentially eliminate the separate statutory definition of an interchangeable biological product. As a result, the ultimate impact, implementation and meaning of the BPCIA continue to be subject to uncertainty.

U.S. Patent Term Extension

After NDA/BLA approval, owners of relevant drug patents may apply for up to a five-year patent extension, under the Hatch-Waxman Amendments provisions that permit the extension of eligible patents as compensation for patent term lost during product development and FDA regulatory review process. The allowable patent term extension is calculated as half of the product's testing phase (the time between IND application and NDA/BLA submission) and all of the review phase (the time between NDA/BLA submission and approval up to a maximum of five years). The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years, and only one patent can be extended. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The USPTO director must determine that approval of the drug covered by the patent for which such interim patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA/BLA has not been submitted.

Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing clinical trials, commercial sales, and distribution of our products. Most countries outside of the United States require that clinical trial applications be submitted to and approved by the local regulatory authority for each clinical study. In addition, whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of countries outside the United States before we can commence clinical trials or marketing of the product in those countries. The approval process and requirements vary from country to country, so the number and type of nonclinical, clinical, and manufacturing studies needed may differ, and the time may be longer or shorter than that required for FDA approval.

European Union (EU) Drug Development

As in the United States, drugs and biologics, which are referred to collectively in Europe as 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 nonclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC 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 transposed and applied the provisions of the Directive differently. This led to significant variations in the

member state regimes. Under the previous regime, before a clinical trial could be initiated, a clinical trial application must have been approved in each of the EU countries where the trial was to be conducted by two distinct bodies: the National Competent Authority (NCA) and one or more Ethics Committees (ECs). All suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial would have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation has since been reformed with the aims of harmonizing and streamlining clinical-trial authorization, simplifying adverse event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Specifically, the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation) came into application on January 31, 2022. The Clinical Trials Regulation is directly applicable in all the EU Member States, repealing the previous Clinical Trials Directive 2001/20/EC. The extent to which ongoing clinical trials are governed by the Clinical Trials Regulation depends on when the Clinical Trials Regulation became applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation became applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial. In addition, use of the new EU-wide application procedure being implemented via the Clinical Trial Information System, became mandatory for new clinical trial application submissions as of February 1, 2023.

With respect to marketing applications for a new medicinal product, there are two types of marketing authorizations available in the European Economic Area (EEA), which is comprised of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein. In the EEA, medicinal products can only be commercialized after obtaining an appropriate Marketing Authorization (MA):

- 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 (CHMP) of the EMA and is valid throughout the entire territory of the EMA. 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 another 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 States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State (RMS). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics (SPC), and a draft of the labeling and package leaflet, which are sent to the other Member States (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.

Similar to the United States, the EU regulatory framework also provides opportunities for market exclusivity. Upon receiving an MA, reference product candidates generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, the data exclusivity period prevents generic applicants from relying on the

nonclinical and clinical trial data contained in the dossier of the reference product when applying for a generic MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

In April 2023, the European Commission proposed widespread changes to the existing pharmaceutical legislation that would, among other things, alter the data exclusivity periods available to MA holders. As of December 2025, the three EU institutions, the European Commission, the European Parliament and the Council of the EU, are in the process of negotiating the final content of the new Directive and Regulation. Once negotiations are complete, the European Parliament and the Council of the EU will vote on whether to approve the Directive and Regulation. If adopted and implemented, these revisions will significantly change several aspects of drug development and approval in the European Union.

EU Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (PSURs).

All new MA applicants must include a risk management plan (RMP) describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk- minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU, which is different from the legal framework in the United States. Moreover, although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each Member State and can differ from one country to another. In recent years, advertising and promotion by pharmaceutical companies in the EU and UK marketplaces have received heightened scrutiny from regulatory authorities and in some cases, fines have been issued.

Brexit and the Regulatory Framework in the United Kingdom (UK)

The UK formally withdrew from the EU on January 31, 2020 (known as Brexit), following which the UK licensing decisions were transferred from the EMA to the Medicines and Healthcare Products Regulatory Agency (MHRA) the UK's regulatory body. Between January 1, 2021 and January 2023, the UK continued to adopt decisions taken by the European Commission on the approval of new marketing authorizations, although companies were required to submit an identical application to the MHRA upon the CHMP positive opinion of the application and the MHRA followed the European Commission decision on approval. In March 2023, the UK government and the European Commission reached agreement on a regulatory framework, referred to as the Windsor Framework. The Windsor Framework became effective January 1, 2025 and changed the system that was previously in effect under the Northern Ireland Protocol, including for the regulation of pharmaceutical products in the UK. Specifically, the MHRA will be responsible for

approving all medicines intended to be marketed in the United Kingdom (including Northern Ireland), while the EMA will no longer be involved in approving medicines intended for sale in Northern Ireland.

Other Healthcare Laws

Manufacturing, sales, promotion and other activities following product approval may also be subject to regulation by other regulatory authorities in the United States in addition to the FDA. Depending on the nature of the product, those authorities may include the Centers for Medicare and Medicaid Services (CMS), other divisions of the U.S. Department of Health and Human Services (HHS), the Department of Justice, the Drug Enforcement Administration, the Federal Trade Commission (FTC), the Occupational Safety and Health Administration, the Environmental Protection Agency and state and local governments.

For example, in the United States, sales and marketing for prescription pharmaceutical products must comply with state and federal fraud and abuse laws. These laws include the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, the Patient Protection and Affordable Care Act (discussed further below), among other things, amended the intent requirement of the federal Anti-Kickback Statute and two of the five criminal healthcare fraud statutes created by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). A person or entity no longer needs to have actual knowledge of these two provisions in the statute or specific intent to violate them; specifically with respect to the prohibition on executing or attempting to execute a scheme or artifice to defraud or to fraudulently obtain money or property of any health care benefit program and the prohibition on disposing of assets to enable a person to become eligible for Medicaid. Moreover, the government may now 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 False Claims Act, which generally prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false 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 material to a false or fraudulent claim to the federal government. Manufacturers can be held liable under the civil False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Biotechnology and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus generally non-reimbursable, uses and purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes.

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 passed by Congress. If pharmaceutical products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. There also are federal transparency requirements under the Physician Payments Sunshine Act that require manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to CMS information related to payments and other transfers of value to physicians, teaching hospitals, and certain advanced non-physician health care practitioners and physician ownership and investment interests. Prescription drug products also must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act.

Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, or the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or

marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act.

Efforts to ensure that business arrangements with third parties comply with applicable state, federal and foreign healthcare laws and regulations involve substantial costs. If a drug company's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting or other federal or state government healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment and reputational harm. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

Healthcare Reform and Potential Changes to Healthcare Laws

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of therapeutic product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell therapeutic product candidates that obtain marketing approval. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. Moreover, among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (ACA), was enacted in March 2010 and has had a significant impact on the healthcare industry in the U.S. The ACA expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to biopharmaceutical products, the ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program. As another example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive healthcare provisions and amendments to existing laws, including a requirement that all manufacturers of drugs and biological products covered under Medicare Part B report the product's average sales price (ASP), to the HHS, beginning on January 1, 2022, subject to enforcement via civil money penalties. We expect that further legislative changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022 (IRA). Among other things, the IRA has multiple provisions that may impact the prices of drug and biological products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of drugs covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, CMS is negotiating drug prices annually for a select number of single source Part D drugs

without generic competition and will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a product is selected by CMS for negotiation, it is expected that the revenue generated from such product will decrease. CMS has begun to implement these new authorities by entering into agreements with pharmaceutical manufacturers to conduct price negotiations and ultimately announcing annual rounds of negotiated prices; those negotiated "maximum fair prices" will be effective initially as of January 1, 2026 (payment year 2026), with subsequent rounds adding additional drugs with negotiated maximum fair prices effective ins subsequent years. However, the IRA's impact on the biopharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. The outcome of such ongoing lawsuits, as well as potential legislative changes enacted by Congress or programmatic changes implemented at CMS by the Trump Administration, may impact the IRA drug price negotiation program in the future.

Separately, the Trump Administration announced the creation of a government website called TrumpRx, which will allow consumers to purchase certain drugs at reduced prices as negotiated between the drug manufacturers and the administration. As of January 2026, the Trump Administration had secured deals with 16 major drug manufacturers to offer certain drugs at most-favored-nation prices.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical 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 December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers (PBMs) and other members of the health care and pharmaceutical supply chain, an important decision that has led to further and more aggressive efforts by states in this area. The FTC in mid-2022 also launched sweeping investigations into the practices of the PBM industry, and published interim reports with its findings in mid-2024 and January 2025, that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements, as PBM reform continues to be a bipartisan priority. In February 2026, President Trump signed into law several PBM regulatory reforms as part of a federal budget package, including but not limited to requirements for PBMs to pass back 100% of rebates and fees to commercial health plan sponsors; to provide extensive informational disclosures related to patients' coverage and benefits; and to accept only bona fide service fees from drug companies when providing services under Medicare Part D. The Department of Labor (DOL) also issued a proposed rule in January 2026 that would mandate specific PBM fee disclosures to self-insured plan fiduciaries under the Employment Retirement Income Security Act (ERISA). If finalized as proposed, the DOL rule would also allow plan fiduciaries to audit those PBM disclosures to confirm accuracy. Additional proposals and legislative changes aimed at PBMs and their business practices are likely to continue to be introduced and considered in Congress and by executive agencies. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including pharmaceutical product developers like us.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services.

Coverage, Pricing and Reimbursement

Sales of our future products 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. There may be significant delays in obtaining coverage and reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. It is time consuming and expensive to seek reimbursement from third-party payors. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover

our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the U.S. In the U.S., third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but they also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Accordingly, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of therapeutics have been a focus in this effort. Recent U.S. federal actions include initiatives incorporating "most favored nation" (international reference pricing) concepts for certain prescription drugs, as well as agency testing of new payment models that could tie Medicare reimbursement or manufacturer rebates to prices in specified reference countries. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. In late 2025, the CMS proposed multiyear pilot models for Medicare Parts B and D that would require manufacturer rebates when U.S. prices exceed prices in designated reference countries; in parallel, the Trump Administration announced a series of manufacturer specific arrangements reflecting most favored nation style pricing commitments in certain programs and channels. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Although the scope, timing and ultimate impact of these most favored nation style initiatives are uncertain and subject to rulemaking, program design and potential legal challenges, if implemented or expanded they could reduce reimbursement or net realized prices for affected products and adversely impact our margins and market access, particularly for products reimbursed under Medicare. Further, if these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products.

Moreover, in some foreign countries, the proposed pricing for a therapeutic product must be approved before it may be lawfully marketed. The requirements governing therapeutic pricing vary widely from country to country. For example, the European Union 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 therapeutic candidates, if approved. Historically, therapeutic candidates launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

U.S. Foreign Corrupt Practices Act

In general, the Foreign Corrupt Practices Act of 1977, as amended (FCPA) prohibits offering to pay, paying, promising to pay, or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business for or with, or in order to direct business to, any person. The prohibitions apply not only to payments made to "any foreign official," but also those made to "any foreign political party or official thereof," to "any candidate for foreign political office" or to any person, while knowing that all or a portion of the payment will be offered, given, or promised to anyone in any of the foregoing categories. "Foreign officials" under the FCPA include officers or employees of a department, agency, or instrumentality of a foreign government. The term "instrumentality" is broad and can include state-owned or state-controlled entities.

Importantly, U.S. authorities that enforce the FCPA, including the Department of Justice, deem most health care professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public health care or public education systems to be "foreign officials" under the FCPA. When we interact with foreign health care professionals and researchers in testing and marketing our products abroad, we must have policies and procedures in place sufficient to prevent us and agents acting on our behalf from providing any bribe, gift or gratuity, including excessive or lavish meals, travel or entertainment in connection with marketing our future products and services or securing required permits and approvals such as those needed to initiate clinical trials in foreign jurisdictions. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the maintenance of books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and the development and maintenance of an adequate system of internal accounting controls for international operations. The SEC is involved with the books and records.

In February 2025, President Trump issued an executive order directing the DOJ to pause enforcement of the FCPA and to issue new enforcement guidelines that take into consideration U.S. national security and the competitiveness of U.S. companies abroad. On June 10, 2025, the DOJ issued guidelines for investigations and enforcement of the FCPA. It is unclear how this presidential directive and DOJ guidelines may affect the biopharmaceutical industry as a whole or our business in particular.

Employees and Human Capital Resources

As of December 31, 2025, we had 77 employees, all of whom were full-time and 45 of whom were engaged in research and development activities. 33 of our employees hold Ph.D. or M.D. degrees. None of our employees are represented by a labor union or covered under a collective bargaining agreement. 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. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-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

We were incorporated in Delaware in April 2021 under the name of ArriVent BioPharma, Inc. Our principal executive offices are located at 18 Campus Boulevard, Suite 100, Newtown Square, PA 19073. Our telephone number is (628) 277-4836. Our website address is www.arrivent.com. Information contained on, or that can be accessible through, our website is not a part of this Annual Report.

Available Information

Our Internet address is www.arrivent.com. We will file or furnish periodic reports and amendments thereto, including our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K (and amendments to those reports), proxy and information statements and other information filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (Exchange Act) with the SEC. The SEC maintains a website that contains reports, proxy and information statement, and other information regarding issuers that file electronically, which may be accessed through the SEC at http://www.sec.gov. Our reports, amendments thereto, proxy statements and other information are also made available, free of charge, on our investor relations website at ir.arrivent.com as soon as reasonably practicable after we electronically file or furnish such information with the SEC. The information contained on the websites referenced in this Annual Report is not incorporated by reference into this filing. Further, our references to website URLs are intended to be inactive textual references only. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Our code of ethics, other corporate policies and procedures, and the charters of our Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee are available through our Internet website at www.arrivent.com.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, the section of this Annual Report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes appearing elsewhere in this Annual Report, before investing in our common stock. The risks and uncertainties described below are not the only ones we face.

Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks occur, our business, operating results and prospects could be materially harmed. In that event, the price of our common stock could decline, and you could lose part or all of your investment. This Annual Report also contains forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in this section below, that represent challenges that we face in connection with the successful implementation of our strategy. The occurrence of one or more of the events or circumstances described in more detail in the risk factors below, alone or in combination with other events or circumstances, may have an adverse effect on our business, cash flows, financial condition, and results of operations. Such risks include, but are not limited to:

- We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We are not currently profitable, and may never achieve or sustain profitability. If we are unable to achieve or sustain profitability, the market value of our common stock will likely decline.
- We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.
- Operating our business requires substantial additional capital to finance our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.
- We currently depend significantly on the success of firmonertinib. If we are unable to advance firmonertinib in clinical development, obtain regulatory approval and ultimately commercialize firmonertinib, or experience significant delays in doing so, our business will be materially harmed.
- Clinical and preclinical development of new biopharmaceutical products involves a lengthy and expensive process with uncertain timelines and outcomes, and results of prior clinical trials and studies our current product candidates are not necessarily predictive of future results. Our other product candidates may not achieve favorable results in our clinical trials or receive regulatory approval on a timely basis, if at all.
- Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials or nonclinical studies could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, which could adversely affect our business, operating results and prospects.
- Use of our current or future product candidates could be associated with adverse side effects, adverse events or other safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue

clinical trials, abandon a product candidate, limit the commercial profile of an approved drug label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

- Several of the ongoing clinical trials for our lead product candidate, firmonertinib, and an ongoing trial for ARR-217, are being conducted outside the United States, including in China. However, the FDA and foreign regulatory equivalents may not accept data from such trials, or may expect proportionately more data from subjects in the United States, in which case our development plans will be delayed, which could materially harm our business.
- Interim, topline and preliminary data from our clinical trials and nonclinical studies that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to timely submit for and obtain regulatory approval for our product candidates, our business will be substantially harmed.
- Firmonertinib has been granted Breakthrough Therapy Designation for the treatment of first-line patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations from the FDA and we may seek Breakthrough Therapy Designation for other product candidates in the future. Even if we apply for Breakthrough Therapy Designation in the future, we might not receive such designation, and even if received, such designation FDA may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.
- Firmonertinib has been granted Fast Track Designation by the FDA for the treatment of patients with NSCLC harboring activating EGFR or HER2 kinase domain mutations, including exon 20 insertion mutations and we may seek Fast Track Designation for other product candidates in the future. Even if we apply for Fast Track Designation in the future, we might not receive such designation, and even if received, such designation may not actually lead to a faster development or regulatory review or approval process. Further, such designation could be withdrawn by the FDA.
- We heavily rely on our exclusive licenses with our partners to provide us with intellectual property rights to develop and commercialize our product candidates. Any termination or loss of significant rights under our agreements with our partners would adversely affect our development or commercialization of our product candidates.
- We currently rely on Chinese third parties for the manufacture of firmonertinib, ARR-217, and ARR-002 for clinical development, expect to rely on such manufacturers for potential future commercial supply of firmonertinib, ARR-217, and ARR-002, and expect to continue to rely on third parties for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities for clinical development of firmonertinib, ARR-217, or ARR-002, or for commercialization of firmonertinib in such quantities at an acceptable cost, which could delay, prevent or impair our development or potential commercialization efforts.
- Even if we receive regulatory approval for any of our current or future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our current and any future product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, if any of them are approved.
- We face significant competition, and if our competitors develop and commercialize technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective, safer, or less expensive than our current and any future product candidates we develop, our business and our ability to develop and successfully commercialize products will be adversely affected.
- We are subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could expose us to criminal sanctions, civil and administrative penalties, contractual damages, reputational harm and diminished profits and future earnings, among other penalties, any of which could harm our results of operations and financial condition.

- If our internal information technology systems, or those used by our CROs, clinical sites, or other contractors or consultants upon which we rely, are or were compromised, become unavailable or suffer security breaches, loss or leakage of data or other disruptions, we could suffer material adverse consequences resulting from such compromise, including but not limited to, operational or service interruption, harm to our reputation, litigation, fines, penalties and liability, compromise of sensitive information related our business, and other adverse consequences.
- We depend heavily on intellectual property licensed from third parties, and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We are not currently profitable, and may never achieve or sustain profitability. If we are unable to achieve or sustain profitability, the market value of our common stock will likely decline.

We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We do not have any products approved for sale and have not generated any revenue since our inception. If our product candidates are not successfully developed, approved and commercialized, we may never generate significant revenue, if we generate any revenue at all. Our net losses were $166.3 million and $80.5 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $404.6 million. Substantially all of our losses have resulted from expenses incurred in connection with in-licensing intellectual property related to, and developing, our product candidates and from general and administrative costs associated with our operations. Our current product candidates, and any future product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for and potentially commercialize our product candidates, seek to identify, assess, acquire, in-license intellectual property related to or develop additional product candidates and operate as a public company. In addition, we are obligated to make milestone payments and royalty payments under certain license agreements and collaboration agreements. For example, we are obligated to pay Allist milestone payments up to an aggregate of $765.0 million upon the achievement of certain development, regulatory and sales milestone events as set forth in the Allist License Agreement, as defined herein. We are also obligated under the Allist License Agreement to pay Allist tiered royalties based on net sales of Licensed Products, as defined herein. Furthermore, we are obligated to pay Lepu Biopharma milestone payments up to an aggregate of $1.17 billion upon the achievement of certain development, regulatory and sales milestone events as set forth in the Lepu Biopharma Agreement, as defined herein. We are also obligated under the Lepu Biopharma Agreement to pay Lepu Biopharma tiered royalties based on net sales of Licensed Products, as defined herein. In addition, we are obligated to pay Aarvik regulatory and sales milestone payments up to an aggregate not to exceed $98.0 million upon the achievement of certain development, regulatory and sales milestone events as set forth in the Aarvik Collaboration Agreement, as defined herein, tiered royalties on aggregate net sales of products developed under the Aarvik Collaboration and commercialized by us or on our behalf at royalty rates in the mid-single digits. See “Business — Licenses, Partnerships and Collaborations — Aarvik Research Collaboration Agreement”. If these payments become due, we may not have sufficient funds available to meet our obligations and our development efforts may be harmed.

To become and remain profitable, we must succeed in developing, obtaining regulatory approvals for, and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials of our current product candidates and any future product candidates, acquiring additional product candidates, obtaining regulatory approvals for our current and any future product candidates, and manufacturing, marketing, and selling any products for which we may obtain regulatory approvals. We may never succeed in these activities and, even if we do, may never generate revenue that is significant

enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates, achieve our strategic objectives or even continue our operations. A decline in the value of our company could also cause stockholders to lose all or part of their investment.

We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in April 2021 and, to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, in-licensing our product candidates, establishing our intellectual property portfolio and conducting research, preclinical studies, and clinical trials. We have not yet completed any pivotal clinical trials, obtained regulatory approvals, manufactured products at commercial scale, or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be accurate.

Operating our business requires substantial additional capital to finance our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.

The development of biopharmaceutical product candidates is capital-intensive. We expect our expenses to substantially increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned clinical trials for our product candidates, and potentially seek regulatory approval for our current and any future product candidates we may develop, acquire or in-license additional product candidates and operate as a public company. In addition, if we are able to progress our product candidates through development and commercialization, we will be required to make milestone and royalty payments to our licensors from whom we have in-licensed intellectual property related to our product candidates. If we obtain regulatory approvals for our current or future product candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reliably estimate the actual amount of financing necessary to successfully complete the development and commercialization of our current or future product candidates.

Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Based on our current operating plan, we believe that our existing cash and cash equivalents, including the proceeds from our recently completed initial public offering, will enable us to fund our operations through at least twelve months from the issuance date of these financial statements. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Our existing cash and cash equivalents, may not be sufficient to complete development of our current product candidates, or any future product candidate, and we will require substantial capital in order to advance our current product candidates, and any future product candidates through clinical trials, regulatory approval and commercialization. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Our ability to raise additional funds may be adversely impacted

by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from factors that include but are not limited to, change in inflation rates, trade sanctions, tariffs, the conflicts in the Middle East, between Russia and Ukraine, potential future U.S. action in Venezuela, and other factors, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts, or even cease operations. We expect to finance our cash needs through public or private equity or debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. In order to obtain financing, we may be required to relinquish rights to some of our technologies or drug candidates or otherwise agree to terms unfavorable to us. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our current product candidates and any future product candidates.

Our future capital requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, type, number, scope, progress, expansions, results, costs and timing of clinical trials and studies of our current product candidates, and any future product candidates we may choose to pursue, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities;
- the costs and timing of manufacturing for our current product candidates, or any future product candidate, including commercial manufacture at sufficient scale, if any product candidate is approved, including as a result of inflation, any supply chain issues or component shortages;
- requirements of regulatory authorities in any jurisdictions in which we may seek approval for our current product candidates, and any future product candidates and our anticipated timing for seeking approval in such jurisdictions;
- the costs, timing and outcome of regulatory meetings and reviews of our current product candidates or future product candidates;
- any delays and cost increases that may result from any health epidemics and outbreaks, including COVID-19 or measles;
- the costs of obtaining, maintaining, enforcing and protecting our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal control over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development, regulatory, Chemistry, Manufacturing, and Controls (CMC), quality, compliance, and commercial personnel;
- the timing and amount of the milestone, royalty or other payments we must make to our licensors, from whom we have in-licensed our current product candidates, or any future licensors;
- the costs and timing of establishing or securing sales and marketing capabilities if any current or future

product candidate is approved;

- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- our ability and strategic decision to acquire or develop future product candidates other than our current product candidates, and the timing of such development, if any;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Conducting clinical trials and nonclinical studies and potentially identifying future product candidates is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and commercialize our current or future product candidates. If approved, our current product candidates, and any future product candidates may not achieve commercial success. Our commercial revenue, if any, will initially be derived from sales of firmonertinib, which we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. We do not have any committed external source of funds. On February 3, 2025, we filed an automatic universal shelf registration on Form S-3 with the SEC, which became effective upon filing, on which we registered for sale any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine (2025 Form S-3), including up to $250 million of common stock which we may offer and sell, from time to time at our sole discretion, under our at-the-market program sales agreement that we entered into with Jefferies LLC (Jefferies) in February 2025 (2025 Sales Agreement).

In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through collaborations, licenses and other similar arrangements, we may be required to relinquish valuable rights to our future revenue streams, product candidates, research programs, intellectual property or proprietary technology, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce, or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we might otherwise prefer to develop and market ourselves, or on less favorable terms than we would otherwise choose.

Risks Related to the Development and Regulatory Approval of Our Product Candidates

We currently depend significantly on the success of our product candidates If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We currently have two product candidates in clinical development, firmonertinib and ARR-217, the intellectual property for which we have individually in-licensed. Firmonertinib is in Phase 3 clinical development and ARR-217, which is in Phase 1 clinical development. Our business presently depends significantly on our ability to successfully develop, obtain regulatory approval for, and commercialize firmonertinib and our other product candidates in a timely manner. This may make an investment in our company riskier than similar companies that have more product candidates in active development and may be able to better sustain the delay or failure of a lead product candidate. In addition, our assumptions about our product candidates' development potential are partially based on the data generated from preclinical studies and clinical trials conducted by our licensors and we may observe materially and adversely different results as we continue to conduct our clinical trials. The success of our product candidates will depend on several factors, including the following:

- successful initiation, enrollment and completion of ongoing and future clinical trials with favorable results in accordance with good clinical practice (GCP) requirements and other applicable rules and regulations;
- acceptance of regulatory submissions by the FDA or comparable foreign regulatory authorities for the conduct of nonclinical studies and clinical trials of our product candidates, including clinical trials conducted outside the United States, including China, and our proposed design of planned nonclinical studies and clinical trials of our product candidates;
- the frequency, severity, and types of adverse events observed, or that we may observe, in nonclinical studies and clinical trials;
- maintaining relationships with contract research organizations (CROs) and clinical sites for the clinical development of our product candidates, and ability of such CROs and clinical sites to comply with clinical trial protocols, current GCP and other applicable requirements;
- demonstrating the safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities, including by establishing a safety database of a size satisfactory to regulatory authorities;
- receipt and maintenance of marketing approvals from applicable regulatory authorities for the initial indication for use and any additional indications, including approvals of NDAs from the FDA, and maintaining any such approvals;
- maintain relationships with our third-party manufacturers and their ability to comply with current Good Manufacturing Practice (cGMP) requirements as well as making arrangements with our third-party manufacturers for, or establishing our own, clinical or commercial manufacturing capabilities at a cost and scale sufficient to support commercialization;
- establishing commercial capabilities and launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- obtaining, establishing, maintaining and enforcing patent and any potential trade secret protection or regulatory exclusivity for our product candidates;
- maintaining an acceptable safety profile of our product candidates following regulatory approval, if any;
- maintaining and growing an organization of people who can develop and, if approved, commercialize our product candidates, if approved; and
- acceptance of our product candidates, if approved, by patients, the medical community and third-party payors.

If we are unable to develop, receive marketing approval for and successfully commercialize our product candidates, or if we experience delays as a result of any of the above factors or otherwise, our business would be significantly harmed.

Clinical and preclinical development of new biopharmaceutical products involves a lengthy and expensive process with uncertain timelines and outcomes, and results of prior clinical trials and studies of our product candidates are not necessarily predictive of future results. Our product candidates may not achieve favorable results in our clinical trials or receive regulatory approval on a timely basis, if at all.

Clinical and preclinical development of new biopharmaceutical candidates is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials or nonclinical studies will be conducted as planned or completed on schedule, if at all, and failure or delays can occur at any time during the trial or study process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of development. The historical failure rate for product candidates in our industry is high, particularly in the earlier stages of development.

The results from preclinical studies or clinical trials of product candidates or a competitor's product candidate in the same class may not predict the results of later clinical trials of our product candidate, and interim, topline, or preliminary results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. We do not know how our product candidates will perform in on-going and future clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on earlier clinical trials and preclinical studies, and many product candidates fail in clinical trials despite very promising early results. Furthermore, although firmonertinib is currently approved and commercially distributed by Allist in China as a first-line therapy to treat classical EGFRm NSCLC based on successful clinical trials conducted within China, there is no guarantee that we will be able to replicate all the results of any prior trials in the indications and doses we are exploring in our on-going and future clinical trials or even if we do, whether such results would lead to approval of the product candidate by the FDA or other health authorities. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. Based upon negative or inconclusive results, we or any future collaborator may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials or delay our ongoing or future clinical trials, which would cause us to incur additional operating expenses and delays and may not be sufficient to support regulatory approval on a timely basis or at all.

As a result, we cannot be certain that our ongoing and planned clinical trials will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials or nonclinical studies could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates for their intended use(s) in humans. Before we can initiate clinical trials for any future product candidates, we must submit the results of nonclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional nonclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our nonclinical development programs. For example, such authorities may ask us to collect more clinical data prior to permitting us to

participate in the adjuvant study of firmonertinib initiated by Allist or to initiate another such study. Moreover, even if we commence clinical trials, issues relating to the safety and efficacy of current or future drug candidates may arise that could cause regulatory authorities to suspend, delay, or terminate such clinical trials. Any such delays in the commencement or completion, or the termination or suspension, of our ongoing and planned clinical trials or nonclinical studies for our product candidates, and any future product candidates could significantly affect our product development timelines and product development costs and harm our financial position.

We do not know whether our planned clinical trials and nonclinical studies will begin on time or be completed on schedule, if at all. The commencement, data readouts and completion of clinical trials and nonclinical studies can be delayed for a number of reasons, including delays related to:

- inability to obtain animals or materials to initiate and generate sufficient nonclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- obtaining allowance from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards (IRBs) or ethics committees (EC) responsible for the oversight of human subjects research conducted at clinical trial sites;
- IRBs/ECs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with GCP requirements or applicable regulatory rules and guidelines in other countries;
- obtaining raw materials for manufacturing sufficient quantities of our product candidates, or obtaining sufficient quantities of combination therapies or other materials needed for use in clinical trials and nonclinical studies;
- obtaining adequate materials for packaging clinical trial material;
- expiration of the shelf life of clinical material for use in clinical trials prior to the enrollment of any of our clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow- up, including subjects failing to remain in our trials due to movement restrictions, health reasons or otherwise resulting from any public health concerns, such as COVID-19 or measles;
- individuals choosing an alternative product for the indications for which we are developing our current or future product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trials, nonclinical studies, manufacturing or incurring greater costs than we anticipate;
- research subjects experiencing severe or serious unexpected treatment-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to our current or future product candidates;

- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization (CMO), as a result of changes in U.S. legislation or otherwise, delays or failure by our CMOs or us to make any necessary changes to such manufacturing process, or failure of our CMOs to produce clinical trial materials in accordance with cGMP regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

In addition, disruptions caused by future public health concerns may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and Ethics Committees or IRBs at the medical institutions where the clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated in whole or in part by us, by the IRBs of the institutions in which such trials are being conducted, by a data safety monitoring board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with GCP, other regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold or other adverse findings, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators or IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as has been done for firmonertinib and intended to be done in the future for firmonertinib and ARR-217 or any other current or future product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, civil unrest, relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study results. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition, many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials, whether in whole or in part, may also ultimately lead to the denial of regulatory approval of a product candidate. We may make formulation or manufacturing changes to our current or future product candidates as a result of changes in U.S. legislation or otherwise, in which case we may need to conduct additional nonclinical studies or clinical trials to bridge our modified product candidates to earlier versions. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our current or future product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, which could adversely affect our business, operating results and prospects.

Patient enrollment is a significant factor impacting the duration of our clinical trials, along with treatment duration and completion of required follow-up periods. Clinical trials may be prolonged, or we may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate as required by the FDA or applicable foreign authorities. For certain of our product candidates, including firmonertinib, the conditions which we may evaluate include limited patient pools from which to draw. In some cases, patient populations are located at specific academic sites focused on such indications, which often host multiple competing clinical trials. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases that we are targeting or may not meet the entry criteria for such trials. We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for our planned clinical trials or in monitoring such patients adequately during and after treatment. As noted above, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. In addition, the process of finding and diagnosing patients may prove costly.

The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If the actual number of patients with these diseases is smaller than we anticipate, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing further development and potential marketing approval of our product candidates. Even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials.

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

- the size and nature of the targeted patient population;
- the severity of the disease or condition under investigation;
- the availability and efficacy of approved therapies for the disease or condition under investigation;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the design of the trial protocol;
- the existing body of safety and efficacy data for the product candidate;
- the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication;
- the proximity of patients to clinical sites;
- continued enrollment of prospective patients by clinical trial sites;
- the eligibility criteria for the trial;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the ability to adequately monitor patients during and after treatment;
- the risk that patients will drop out of a trial before completing all site visits;

- delays or difficulties in enrollment and completion of studies due to travel or quarantine policies, or other factors, including those related to COVID-19 or future pandemics or epidemics; and
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available approved or investigational therapies, including any products that may be approved for, or any product candidates under investigation for, the indications we are investigating.

Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. In addition, any negative results we may report in clinical trials of our product candidate or any negative results a competitor may report in clinical trials of the competitor's product candidate in the same class, may make it difficult or impossible to recruit and retain patients in other clinical trials of our product candidate.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible. For example, the impact of public health epidemics may delay or prevent patients from enrolling or from receiving treatment in accordance with the protocol and the required timelines, which could delay our clinical trials, or prevent us or our partners from completing our clinical trials at all, and harm our ability to obtain approval for such product candidate. Further, if patients drop out of our clinical trials, miss scheduled doses or follow-up visits, or otherwise fail to follow clinical trial protocols for any reason, the integrity of data from our clinical trials may be compromised or not accepted by the FDA or applicable foreign authorities, which would represent a significant setback for the applicable program. In addition, we rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance. Such delays or failures could adversely affect our business, operating results and prospects.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain regulatory approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

Use of our current or future product candidates could be associated with adverse side effects, adverse events or other safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved drug label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

As is the case with biopharmaceuticals generally, adverse side effects associated with the use of firmonertinib have been observed and it is likely there may be adverse side effects with our other product candidates and any future product candidates we may develop. Results of our ongoing and future clinical trials of firmonertinib or other product candidates could reveal a high and unacceptable severity and prevalence of expected or unexpected side effects or unexpected characteristics. Undesirable side effects caused by our product candidates when used alone or in combination with approved or investigational drugs could cause us or regulatory authorities to interrupt, delay or partially or completely halt clinical trials and could result in a restrictive prescription drug label, post-approval requirements, or lead to the delay of the planned clinical development, or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences could severely harm our business, prospects, operating results and financial condition. The severity of adverse events (AEs) is described by grade on a scale of increasing severity from Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), Grade 4 (life-threatening) and Grade 5 (death). Serious adverse events (SAEs) are adverse events that are life threatening, require or prolong hospitalization, result in persistent or significant disability/incapacity, result in congenital anomalies or birth defects, or any other medical event which investigators judge to represent significant hazards. It should be noted that "Severe" and "Serious" are not synonymous as not all AEs that are severe (Grade 3) meet the criteria for SAE while Grade 4 (life-threatening) and Grade 5 (death) AEs are SAEs. AEs and SAEs that are

determined to be related to the drug(s) being tested are reported as TRAEs and TRSAEs. TRAEs leading to discontinuation of study drug(s) are commonly reported to indicate the manageability of treatment-related toxicities. In the FURLONG trial, TRSAEs were observed in ten out of 178 treated patients and six out of 178 patients discontinued participation in the trial as a result of TRAEs. In the FAVOUR trial, as of the December 5, 2024 data cut-off date, TRSAEs were observed in seven out of 90 of the treated patients and three out of 90 patients discontinued participation in the trial as a result of TRAEs. The most frequent TRAEs (≥20%) in the FAVOUR trial as of December 5, 2024 were diarrhea, anemia, aspartate aminotransferase increased, alanine aminotransferase increased, blood creatinine increased, mouth ulceration, rash, white blood cell count decreased. Isolated cases of Grade ≥3 reversible hepatic transaminases accompanied with increased total bilirubin have been observed at firmonertinib dose levels higher than 80 mg daily. In the FURTHER trial, based on data as of July 3, 2025, TRSAEs were observed in eleven out of 116 of the treated patients and 8 out of 116 patients discontinued participation in the trial as a result of TRAEs. In the Furmo-003 trial (a phase 2 trial conducted by Allist in China in EGFRm NSCLC patients with exon 20 insertion mutations on/after platinum-based therapy), based on data as of September 30, 2025, TRSAEs were observed in 11 out of 71 patients treated with firmonertinib, and four out of 71 patients discontinued study treatment due to TRAEs. Overall, the most common TRSAEs (defined as ≥1%), across the FURLONG, FAVOUR, Furmo-003 and FURTHER trials were platelet count decreased, 1.3% (6 out of 455), pneumonitis/ILD, 1.1% (5 out of 455), and aspartate aminotransferase increased, 1.1% (5 out of 455). The discontinuation rate due to TRAEs across the FURLONG, FAVOUR, Furmo-003 and FURTHER trials was 4.6% (21 out of 455). See "Business — Firmonertinib: Our Lead Development Candidate" for additional information. See "Business — Firmonertinib: Our Lead Development Candidate" for additional information.

Moreover, if our current or future product candidates are associated with undesirable side effects in clinical trials or demonstrate characteristics that are unexpected in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may elect to interrupt, delay, or abandon their development in whole or in part or limit their development to more narrow uses, lower doses, or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the potential approval and commercial expectations for the product candidate if approved. We may also be required to modify our development and clinical trial plans based on findings in our ongoing clinical trials or based on the findings of our competitors' ongoing clinical trials of molecules in the same class. Many compounds that showed promise initially have later been found to cause side effects that prevented further development of the compounds.

If our current or future product candidates receive marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- we may be required to recall a product or change the way such product is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or a contraindication;
- we may be required to change the way a product is distributed or administered, conduct additional clinical trials or conduct post-marketing studies or surveillance studies;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients;
- sales of the product may decrease significantly or the product could become less competitive; and
- our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We may not be successful in our efforts to investigate firmonertinib or our other current product candidates in additional indications. We may expend our limited resources to pursue, acquire or license a new product candidate or a particular indication for our product candidates and fail to capitalize on such product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific indications for firmonertinib to treat NSCLC. We may fail to generate additional clinical development opportunities for firmonertinib for a number of reasons, including that firmonertinib may, in indications we are seeking or may seek in the future, on further study, be shown to have harmful side effects, limited to no efficacy, or other characteristics that suggest it is unlikely to receive marketing approval and achieve market acceptance in such additional potential indications. Our resource allocation and other decisions may cause us to fail to identify and capitalize on viable potential product candidates or additional indications for firmonertinib. Our spending on current and future research and development programs for new product candidates or additional indications for existing product candidates may not yield any commercially viable product candidates or indications. If we do not accurately evaluate the commercial potential or target market for a particular indication or product candidate, we may fail to develop such product candidate or indication, we may relinquish valuable rights to that product candidate through collaborations, license agreements and other similar arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights to such indication or product candidate, or we may negotiate less advantageous terms for any such arrangements than is optimal.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

We may in the future develop our product candidates in combination with other therapies, and safety or supply issues with combination-use products may delay or prevent development and approval of our product candidates.

We may in the future develop our product candidates in combination with one or more cancer therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidates or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. Similarly, if the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or similar regulatory authorities outside of the United States may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA or a similar regulatory authority outside of the United States. We may be unable to effectively identify and collaborate with third parties for the evaluation of our product candidates in combination with their therapies. We will not be able to market and sell any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. The regulations prohibiting the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other government agencies. In addition, there are additional risks similar to the ones

described for our products currently in development and clinical trials that result from the fact that such cancer therapies are unapproved, such as the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA or a similar regulatory authority outside of the United States does not approve these other drugs or revokes approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval of or market such product.

Several of the ongoing clinical trials for our lead product candidate, firmonertinib, and an ongoing trial for ARR-217 are being conducted outside the United States, including in China, and we expect to conduct future clinical trials of firmonertinib and our other product candidates outside the United States, including in China. However, the FDA and foreign regulatory equivalents may not accept data from such trials, or may expect proportionately more data from subjects in the United States or the corresponding foreign jurisdiction, in which case our development plans will be delayed, which could materially harm our business.

Several of the ongoing clinical trials for our lead product candidate, firmonertinib, are being conducted both inside and outside of the United States, including in China. Specifically, we have enrolled patients globally in our FURVENT and FURTHER trials and are enrolling patients globally in our ALPACCA trial. Furthermore, our partner Allist is conducting the FAVOUR trial in China. The initial clinical study of ARR-217 is also being conducted in China. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. The data from foreign clinical trials must also be representative of the Unites States patient population. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. In February 2022, the FDA publicly rebuked an oncology product sponsor for submitting a marketing application with Phase III clinical data solely from China. The FDA's Oncologic Drug Advisory Committee recently noted that the data from a global study of a hematology drug did not appear to be representative of the U.S. population, pointing to apparent differences in results from Asian and Non-Asian regions and proportionally smaller U.S. sample size, the lack of regional stratification in the study design, and potential imbalances in patient characteristics. The FDA subsequently issued a CRL for the drug's application for marketing authorization. Members of Congress have also raised national security concerns related to U.S. clinical trial sponsors utilizing study sites in China that may be owned or operated by the Chinese military. It remains to be seen whether the current administration and/or the 119th Congress (2025-26) take steps to restrict or limit the conduct of clinical research activities in China or other jurisdictions, or to otherwise require additional due diligence checks or oversight by sponsors.

Many foreign regulatory authorities have similar approval requirements. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction, including any trials conducted in China. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted, which may increase costs or time required to complete the clinical trial.

Conducting clinical trials outside the United States, particularly in China, also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- inconsistent standards for reporting and evaluating clinical data and adverse events;
- infectious disease pandemics or epidemics or any other form of future public health emergency;
- diminished protection of intellectual property in some countries; and
- political instability, civil unrest, war or similar events that may jeopardize our ability to commence, conduct or complete a clinical trial and evaluate resulting data.

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

From time to time, we may publicly disclose interim, topline or preliminary data from our clinical trials and preclinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, in September 2024, we announced positive interim proof-of-concept data from the FURTHER trial of firmonertinib in first-line patients with locally advanced or metastatic EGFRm NSCLC with PACC mutations. In this interim readout, 64% of patients (n=14 out of 22 patients) were observed to experience a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression as measured by RECIST 1.1 criteria. Median DOR had not yet been reached, with 90.9% (n=20/22) of patients with confirmed responses remaining on study. We subsequently announced the final analysis of the FURTHER trial, reporting a 16.0 months mPFS with firmonertinib 240 mg by BICR in first-line patients and a confirmed overall response rate (cORR) 68.2%, DOR 14.6 months by BICR in first-line patients, and confirmed CNS responses with firmonertinib including CRs by BICR. Additionally, we reported that the most frequent treatment-related adverse events include diarrhea, hepatic enzyme elevation, rash, stomatitis, and dry skin.

We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

Interim data from clinical trials that we may complete are further subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, topline, or preliminary data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

In addition, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. Moreover, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we

determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business.

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

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

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. We are not permitted to market our product candidates in the United States until we receive regulatory approval of an NDA from the FDA. The process of obtaining such regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA and comparable regulatory authorities have substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval of a product candidate is never guaranteed. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe available nonclinical or clinical data support the safety or efficacy of our product candidates, such data may not be sufficient to obtain approval from the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional nonclinical studies or clinical trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or execution of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- we may be unable to demonstrate to such authorities that a product candidate’s clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities.

Even if we eventually complete clinical trials and receive approval of an NDA or comparable foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and/or the implementation of a Risk Evaluation and Mitigation Strategy (REMS), which may be required because the FDA believes it is necessary to ensure safe use of the product after approval. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

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

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction. For example, firmonertinib has been approved by the National Medical Products Administration (NMPA) of China and is currently commercially distributed in China by Allist as a first-line treatment of locally advanced or metastatic NSCLC patients with classical EGFRm as well as pre-treated patients with T790M mutations and more recently in patients who have failed first line therapy in Exon20 insertion mutations. Even if the NMPA or a foreign regulatory authority grants marketing approval of one of our product candidates, it does not mean that the FDA or comparable regulatory authorities in other jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in such countries, including the United States. However, a failure or delay in obtaining marketing approval in one jurisdiction may negatively impact the marketing approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials because clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate also must be approved for reimbursement before it can be offered for sale in that jurisdiction. In some cases, the price that we intend to charge for our future commercial products is also subject to approval.

Obtaining foreign marketing approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed, which would adversely affect our business, prospects, financial condition, and results of operations.

Firmonertinib has been granted Breakthrough Therapy Designation for the treatment of first-line patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations from the FDA and we may seek Breakthrough Therapy Designation for other product candidates in the future. Even if we apply for Breakthrough Therapy Designation in the future, we might not receive such designation, and even if received, such designation may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

We received Breakthrough Therapy Designation for firmonertinib for the treatment of first-line patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations from the FDA in October 2023, and we may seek such designation for other product candidates in the future. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development. Drugs designated as Breakthrough Therapies are also eligible for accelerated approval.

The FDA has discretion to determine whether the statutory criteria have been met and whether to grant a Breakthrough Therapy Designation to a product candidate. Accordingly, even if we believe, after completing early clinical trials, that one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and not make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and does not change the standard for approval by the FDA. In addition, even after granting Breakthrough Therapy Designation to a product candidate, the FDA may later decide that such product candidates no longer meet the conditions for qualification and withdraw such designation.

Firmonertinib has been granted Fast Track Designation by the FDA for the treatment of patients with NSCLC harboring activating EGFR or HER2 kinase domain mutations, including exon 20 insertion mutations and we may seek Fast Track Designation for other product candidates in the future. Even if we apply for Fast Track Designation in the future, we might not receive such designation, and even if received, such designation may not actually lead to a faster development or regulatory review or approval process. Further, such designation could be withdrawn by the FDA.

In January 2022, the FDA granted Fast Track designation to firmonertinib for the treatment of patients with NSCLC harboring activating EGFR or HER2 kinase domain mutations, including exon 20 insertion mutations. If a drug candidate is intended for the treatment of a serious or life-threatening disease or condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need for this disease or condition, a product sponsor may request a Fast Track designation from the FDA. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track designated product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA/BLA is submitted, the application may be eligible for priority review. An NDA/BLA submitted for a Fast Track designated product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA/BLA 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/BLA, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

If we seek Fast Track designation from the FDA, we may not receive it and even if we receive such designation, it does not ensure that we will receive marketing approval or that approval will be granted in any particular time frame. Many product candidates that have received Fast Track designation have ultimately failed to obtain approval. We also may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it is no longer supported by data from our clinical development program. Fast Track designation alone also does not guarantee qualification for the FDA's priority review procedures for marketing applications.

Even though firmonertinib has been granted an Orphan Drug Designation in the United States for the treatment of NSCLC, there can be no guarantee that we will maintain orphan status for the product candidate, that we will be able to secure orphan status for future candidates should we seek such designation, or that we will receive approval for any product candidate with an Orphan Drug Designation or benefit from a period of orphan exclusivity following a future product approval.

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation to a drug or biologic intended to treat a rare disease or condition or for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for a disease or condition will be recovered from sales in the United States for that drug or biologic. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Even with orphan drug status, exclusive marketing rights in the United States may be limited if we seek FDA marketing approval for an indication broader than the candidate's orphan designated indication. Additionally, any candidate that initially receives orphan drug status designation may lose such designation if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

We received Orphan Drug Designation for firmonertinib for the treatment of NSCLC with EGFRm or HER2 mutations or HER4 mutations in February 2024, and we may seek orphan status for future indications or product candidates. We are not guaranteed to maintain or receive Orphan Drug Designation for our current or future product candidates, and if our product candidates that were granted Orphan Drug Designation were to lose their status as an orphan or their eligibility for orphan exclusivity upon approval, our business and results of operations could be materially adversely affected. While orphan status for any of our products, if granted or maintained, would provide market exclusivity in the United States for the time periods specified above, we would not be able to exclude other companies from manufacturing and/or selling products using the same active ingredient for the same indication beyond the exclusivity period applicable to our product on the sole basis of orphan drug status. In addition, orphan exclusivity does not block the approval of a different drug or biologic for the same rare disease or condition, nor does it block the approval of the same drug or biologic for different conditions.

We may seek to utilize the FDA's accelerated approval pathway for certain firmonertinib indications and may pursue this pathway for future therapeutic candidates. There is no assurance that, upon receipt of such future marketing application, if any, the FDA will agree to file it and conduct a substantive review of the data or that FDA will agree that we have met the substantial evidence of effectiveness and safety standard necessary to support marketing approval. If unable to obtain approval under the accelerated approval pathway, we may be required to conduct additional nonclinical studies or clinical trials beyond those that we currently contemplate for certain firmonertinib indications, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA for certain firmonertinib indications, or for other future therapeutic candidates for which the accelerated approval pathway may be appropriate, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

Under the accelerated approval provisions in the FDC Act and the FDA's implementing regulations, the FDA may grant accelerated approval to a therapeutic product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint, or intermediate clinical endpoint, that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than 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. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity, mortality, or other clinical benefit.

The FDA may not accept any future application for accelerated approval for firmonertinib in NSCLC patients diagnosed with PACC mutations, may not grant marketing approval on a timely basis, or may not grant approval at all. The FDA or foreign regulatory authorities could require us to conduct further studies prior to considering our application or granting approval of any type. We might not be able to fulfill the FDA's requirements in a timely manner or at all, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA. A failure to obtain accelerated approval or any other form of expedited development, review, or approval for firmonertinib would result in a longer time period to commercialization of firmonertinib, would increase the cost of development of firmonertinib and could harm our competitive position in the marketplace. Following high-profile voluntary withdrawals of accelerated approval indications by several oncology sponsors as a result of post-approval trials failing to verify their drug products' clinical benefit for those indications, which resulted in December 2022 amendments by Congress to the FDA's authorities related to accelerated approval, public scrutiny of the accelerated approval pathway is likely to continue and may lead to further legislative and/or administrative changes in the future.

Moreover, even if we receive accelerated approval from the FDA for certain firmonertinib indications, we will be subject to rigorous post-marketing requirements, including the completion of one or more confirmatory post-approval clinical trials to verify the clinical benefit of the product in that patient population, and submission to the FDA of all promotional materials for review prior to their dissemination. The FDA could also seek to withdraw accelerated approval for multiple reasons, including if we fail to conduct any required post-approval study, a post-approval study does not confirm the predicted clinical benefit, other evidence shows that the product is not safe or effective under the conditions of use, or we disseminate promotional materials that are found by the FDA to be false and misleading. Products that receive accelerated approval may be subject to expedited withdrawal procedures if post-approval studies fail to verify the predicted clinical benefit. In addition, as noted above, Congress recently provided the FDA with new statutory authorities to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these amendments to the FDC Act, the agency may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted. If we fail to receive accelerated approval for firmonertinib in this patient population or fail to comply with the post-marketing requirements, our business, results of operations, prospects and the price of our common stock may be materially and adversely affected.

Disruptions at the FDA and other government agencies caused by funding shortages, mass layoffs, or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, reviewed, approved or commercialized in a timely manner or at all, which could negatively impact our business or our ability to access the public markets.

The ability of the FDA and other government agencies to review and approve new medical products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including during the fourth quarter of 2025, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities during that period. Additionally, over the past year the FDA has experienced significant and rapid fluctuations in leadership and scientific review personnel, which may be key contributing factors in multiple reported delays in agency decision making on marketing applications and agency requests for additional data that are inconsistent with prior regulatory feedback. The impact of the current administration's mass layoffs at the agency, as well as at other governmental offices with which we interact is unclear at this time.

Separately, during the heights of the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points, and regulatory authorities outside the United States adopted similar policy measures. Future emerging infectious disease outbreaks, epidemics or pandemics may lead to such policy and resource prioritization changes in the future. If a prolonged government shutdown or slowdown occurs, or if global health concerns similar to COVID-19 prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and our business will be harmed.

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the regulatory submissions or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical trials, receipt of regulatory approval or the commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of authorizations by the FDA and comparable foreign regulatory authorities, and the timing thereof;
- other actions, decisions or rules issued by regulators;
- the efforts of our collaborators with respect to the commercialization of our products, if any; and
- the securing of, costs related to, and timing issues associated with, commercial product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of any of our product candidates may be delayed, and our business, results of operations, financial condition and prospects may be adversely affected.

Risks Related to Our Reliance on Third Parties

We heavily rely on our exclusive licenses with our partners to provide us with intellectual property rights to develop and commercialize our product candidates. Any termination or loss of significant rights under our agreements with our partners would adversely affect our development or commercialization of our product candidates.

Under the Allist License Agreement we have, among other things, secured an exclusive, royalty-bearing, and sublicensable license under certain intellectual property (including patents and know-how) owned or controlled by Allist to develop and commercialize any product containing firmonertinib or any of its salts or derivatives (the Licensed Compound) as an active ingredient of a product (the Licensed Product), which is led by a joint collaboration committee (the Collaboration Committee), comprising of representatives from both Allist and us. We granted Allist a non-exclusive sublicensable license to certain information, data, results and improvements related to the Licensed Product. Either party has the right to terminate the Allist License Agreement, subject to specified cure periods, for the material breach by the other party or the bankruptcy or insolvency of the other party. If the Allist License Agreement is terminated for any

reason, including as a result of our failure to meet our obligations under the Allist License Agreement to make any milestone payments or royalties to Allist, our business and operations would be materially harmed.

We are obligated to pay Allist milestone payments up to an aggregate of $765 million upon the achievement of certain development, regulatory and sales milestone events. In addition, we are obligated to pay Allist tiered royalties based on net sales of Licensed Products. In addition, upon termination of the Allist License Agreement by either Allist or us, (i) if the termination is for any reason other than by us for the material breach by Allist, then we may at our discretion continue to distribute and sell Licensed Products for a reasonably sufficient wind-down period up to 24 months from the termination, in accordance with the Allist License Agreement, and are obligated to continue to make all applicable payments to Allist for the Licensed Products we sell, and (ii) if the termination is by us for the material breach by Allist, then we would have the right to continue under the Allist License Agreement in lieu of the termination but with our milestone and royalty payment obligations substantially reduced. If these payments become due, we may not have sufficient funds available to meet our obligations and our development efforts may be harmed.

Furthermore, we entered into the Allist Collaboration Agreement with Allist to govern the conduct of Global Study. See "Business — Licenses, Partnerships and Collaborations — Allist Agreements." Pursuant to the Allist Collaboration Agreement, if either party or both parties wish to jointly conduct a Global Study, one or both parties, as the case may be, will prepare and submit the proposed strategy, internal process timeline, along with other required documents for such proposed Global Study to the Collaboration Committee for its review and approval before the protocol filing with any regulatory authorities. If the Collaboration Committee cannot come to a mutual agreement on the proposed strategy or any other particular matter, this could delay our ability to develop or commercialize firmonertinib, which could have a material adverse effect on our business and operations. Additionally, if we do not receive all of the necessary products, information, reports and data from Allist to which we are entitled under the Allist Collaboration Agreement in a timely manner, our business could be materially harmed.

Reported data or other clinical development announcements by third parties, including Allist, may adversely affect our clinical development plan.

Allist is currently conducting clinical studies in China with firmonertinib, including a Phase 1b trial and a phase 2 trial in EGFRm NSCLC patients with exon 20 insertion mutations. Collaborators of Allist are also conducting additional clinical studies of firmonertinib in a variety of cancers. Allist is also commercializing firmonertinib in China. If announcements by Allist or other third parties with whom we collaborate, or by third parties with whom Allist collaborates, now or in the future, are unfavorable with respect to their clinical trials, or with respect to post-approval monitoring, our clinical development plans may be adversely affected. Further, even if announcements by such third parties are favorable with respect to their clinical trials, our planned clinical trials for firmonertinib, and any future clinical trials we may conduct, differ from their clinical trials and investors should not place undue reliance upon any of such third parties' reported data or other clinical development announcements.

We rely on, and intend to continue to rely on, third parties to conduct, supervise and monitor our clinical trials and nonclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidates, and any future product candidates may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We are dependent on third parties to conduct our clinical trials and preclinical and nonclinical studies. Specifically, we rely on, and intend to continue to rely on, medical institutions, clinical investigators, CROs, such as Fortrea, Inc., Icon Clinical Research Limited, and Syneos Health, LLC, and consultants to conduct nonclinical studies and clinical trials, in each case in accordance with our study protocols and applicable regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these studies or trials and the subsequent collection and analysis of data. Though we expect to carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, while we have and will have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our

clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards and requirements, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. In addition, we and our CROs are required to comply with GLP and GCP requirements, as applicable, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities related to the conduct of nonclinical studies and clinical trials, respectively. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GLP or GCP or other requirements, the collected nonclinical data or the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional nonclinical studies or clinical trials before approving our marketing applications, if ever. Furthermore, our clinical trials must be conducted with materials manufactured in accordance with cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position. In addition, principal investigators for our clinical trials are expected to serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent us from receiving regulatory approval for, or commercializing, firmonertinib, our other product candidates, and any future product candidates.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, in a timely manner or at all. Switching or adding CROs, investigators and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We currently rely on Chinese third parties for the manufacture of firmonertinib, ARR-217, and ARR-002 for clinical development, expect to rely on such manufacturers for potential future commercial supply of firmonertinib, ARR-217, and ARR-002, and expect to continue to rely on third parties for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities for clinical development of firmonertinib, ARR-217, or ARR-002, or for commercialization of firmonertinib in such quantities at an acceptable cost, which could delay, prevent or impair our development or potential commercialization efforts.

We do not own or operate manufacturing facilities and have no plans to develop our own clinical or commercial-scale manufacturing capabilities. We rely on Chinese third parties, and expect to continue to rely, on such third parties for the manufacture of firmonertinib, ARR-217, and ARR-002, and related raw materials for clinical development, as well as for commercial manufacture of firmonertinib, should firmonertinib receive marketing approval. The facilities used by third-party manufacturers to manufacture our product candidates must be approved by the FDA and any comparable foreign regulatory authority pursuant to inspections that will be conducted after we submit an NDA/BLA to the FDA or make any comparable submission to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of products. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign

regulatory authority, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities.

In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any comparable foreign regulatory authority does not approve these facilities for the manufacture of our current product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our current product candidates if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations also could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of our current product candidates or any future products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and our financial position.

Our or a third party's failure to execute on our manufacturing requirements on commercially reasonable terms, in a timely manner and in compliance with cGMP or other regulatory requirements could adversely affect our business in a number of ways, including:

- an inability to initiate or complete clinical trials of our current product candidates, or any other future product candidates in a timely manner;
- delay in submitting regulatory applications, or receiving marketing approvals for our current product candidates or any future product candidates;
- subjecting third-party manufacturing facilities or our potential future manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our current or future product candidates; and
- in the event of approval to market and commercialize our current or future product candidates, an inability to meet commercial demands for our current or future product candidates.

In addition, we do not have any long-term commitments or supply agreements with any third-party manufacturers. We may be unable to establish any long-term supply agreements with third-party manufacturers or to do so on acceptable terms, which increases the risk of failing to timely obtain sufficient quantities of our product candidates or such quantities at an acceptable cost. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product candidates according to our specifications;
- failure to obtain adequate raw materials and other materials required for manufacturing;
- failure to manufacture our product according to our schedule or at all;
- failure to successfully scale up manufacturing capacity, if required;
- misappropriation of our proprietary information, including any potential trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval or jeopardize our ability to commence or continue commercialization of our current product candidates or any future product candidates, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required

raw materials used in the manufacture of our product candidates. If our existing or future third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Without additional suppliers of required raw materials, we may also be unable to meet the commercial needs of a commercial launch of any future product candidates.

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

A portion of our product development and manufacturing for our current product candidates takes place in China through third-party manufacturers. A significant disruption in the operation of those manufacturers, a trade war or political unrest in China, or a change in the regulatory framework in the United States or China, could materially adversely affect our business, financial condition and results of operations.

Currently, we rely on and have agreements with two third-party contract manufacturers, Raybow and WuXi STA, to supply the drug substance for firmonertinib for use in ongoing and planned clinical trials. We also rely on and have an agreement with WuXi STA to manufacture the clinical trial supplies of firmonertinib drug product and supplies for initial commercial launch in the United States, if approved. Both third-party contract manufacturers are located in China, and we expect to continue to use such third-party manufacturers for such firmonertinib drug substance and drug product supplies. We expect to rely on manufacturers in China for ARR-217 drug substance and drug product for use in clinical studies and also expect to rely on WuXi XDC for the manufacture of ARR-002 for initial clinical studies. Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs, whether as a result of a natural disaster, infectious disease outbreak, or other causes could impair our ability to operate our business on a day-to-day basis and to continue our development of our product candidates, and commercialization of firmonertinib, if approved. Furthermore, since these manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U.S. or Chinese governments, political unrest or unstable economic conditions in China.

The National Defense Authorization Act for Fiscal Year 2026 includes a section titled, "Prohibition on Contracting with Certain Biotechnology Providers," also known as the BIOSECURE Act, aimed at discouraging federal contracting with certain biotechnology companies for biotechnology equipment or services in China and other countries of concern. The statute prohibits federal executive agencies from procuring any biotechnology equipment or service from a biotechnology company of concern (BCC) or contracting with any such company or any entity that procures or uses equipment or services from a BCC. Any company on the Department of Defense's Chinese Military Companies List (1260H list) is considered a BCC under the new law and the White House Office of Management and Budget is empowered to designate companies as BCCs based on consultations with Cabinet Secretaries and other key leaders from the executive branch. Such prohibitions may limit our ability to obtain federal government grants for research involving our products, if approved, or product candidates manufactured in China or to enter contracts to sell any such products, if approved, to the federal government. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. For example, in the event that we need to switch our third-party manufacturer of firmonertinib or ARR-002 from WuXi STA or related entities, we anticipate that the complexity of the manufacturing process may impact the amount of time it may take to secure a replacement manufacturer. The delays associated with the verification of a new manufacturer, once we are able to identify an alternative source, could negatively affect our ability to develop product candidates in a timely manner or within budget, which could materially adversely affect our business, financial condition and results of operations.

Changes in United States trade policy, including recently announced or potential future tariffs, could have a material adverse impact on our business, financial condition, and results of operations. The imposition of new tariffs or increases in existing tariffs on goods imported from or expected to be imported from countries where we or our suppliers operate could result in higher costs for materials or components essential to our operations. For example, in April 2025, the United States imposed broad tariffs on imports from virtually all countries, with particularly high tariffs on imports from

China. Since this announcement, most tariffs for countries other than China have been suspended temporarily. In response to tariffs, some countries have implemented retaliatory tariffs on U.S. goods, while others seek to negotiate agreements regarding U.S.-imposed tariffs. Historically, tariffs have led to increased trade and political tensions and, to date, the outcome of the negotiations between the United States and the various countries is not yet clear. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations.

We have entered into and in the future may seek to enter into collaborations, license agreements and other similar arrangements and may not be successful in doing so, and even if we are, we may relinquish valuable rights and may not realize the benefits of such relationships, and our collaborations would be subject to other risks attendant to third party relationships, including inability to prevent or control actions taken or not taken by such third parties which may adversely impact us.

We are currently collaborating with third parties to develop certain of our potential drug candidates. For example, we are collaborating with Allist with respect to certain aspects of firmonertinib and are collaborating with Lepu Biopharma with respect to ARR-217. In the future, we may seek to enter into collaborations, joint ventures, license agreements and other similar arrangements for the development or commercialization of our current product candidates, and any future product candidates, due to capital costs required to develop or commercialize the product candidate or manufacturing constraints. For example, certain of the cancer disease areas that we believe our product candidates address require large, costly and later-stage clinical trials, which a collaboration partner may be better positioned to finance and/or conduct. In addition, a component of our strategy is to maximize the commercial value of our current and future product candidates, which may also strategically align with partnering commercial rights with partners that have large and established sales organizations. To the extent that we decide to enter into collaborations, joint ventures, license agreements and other similar arrangements, we may not be successful in our efforts to establish or maintain such collaborations because our research and development pipeline may be insufficient, any future product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time-consuming and complex. Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us. For example, we may need to relinquish valuable rights to our future revenue streams, research programs, intellectual property or product candidates, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. In addition, if we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a collaboration, license or strategic transaction, we will achieve an economic benefit that justifies such transaction.

Furthermore, we may not be able to maintain such collaborations if, for example, the development or approval of a product candidate is delayed, the safety of a product candidate is questioned or the sales of an approved product candidate are unsatisfactory.

Collaborations involving our current or future product candidates would pose significant risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected or at all;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;

- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to any product candidate that achieves regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays in or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly enforce, maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborators may not provide us with timely and accurate information regarding development, regulatory or commercialization status or results, which could adversely impact our ability to manage our own development efforts, accurately forecast financial results or provide timely information to our stockholders regarding our out-licensed product candidates;
- we may be required to invest resources and attention into such collaboration, which could distract from other business objectives;
- disputes may arise between the collaborators and us regarding ownership of or other rights in the intellectual property generated in the course of the collaborations;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all;
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated; and
- collaborations may be terminated, including for the convenience of the collaborator, prior to or upon the expiration of the agreed upon terms and, if terminated, we may find it more difficult to enter into future collaborations or be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Any termination of collaborations we currently depend on or may enter into in the future, or any delay in entering into collaborations related to our current or future product candidates, could delay the development and

commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Commercialization of Firmonertinib, Our Other Product Candidates, and any Future Product Candidates

Even if we receive regulatory approval for any of our current or future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our current and any future product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, if any of them are approved.

Any regulatory approvals that we may receive for our other current or any future product candidates will require the submission of various post-marketing reports to regulatory authorities, will subject us to surveillance requirements to monitor the safety and efficacy of the product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications and may include burdensome post-approval study or risk management requirements. For example, the FDA may require REMS as a condition of approval of our current or any future product candidates, which could include requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our current or future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for such products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, facility registration, and continued compliance with cGMPs for product manufacturing and GCP requirements for any clinical trials that we conduct post-approval. Manufacturers of approved products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. In addition, should accelerated approval be granted to any of our product candidates, we will be required to complete confirmatory clinical trials to verify the drug's clinical benefit(s) and to make certain mandatory submissions to the FDA that are not applicable to drug products with "full" or traditional FDA marketing approvals (*i.e.*, those not subject to accelerated approval requirements).

Failure to comply with regulatory requirements or later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, may result in a regulatory agency imposing restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- fines, restitutions, disgorgement of profits or revenue, warning letters, untitled letters, or adverse publicity;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions and the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our current or future product candidates and to generate revenue, could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability. In addition, the U.S. Supreme Court's June 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, or changes.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA and other regulatory agencies strictly regulate the marketing, labeling, advertising, and promotional claims that may be made about prescription drug products, such as our current or future product candidates, if approved. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. However, companies may share truthful and not misleading information that is not inconsistent with the labeling, and the FDA has recently published guidance for industry outlining modernized recommendations for how drug manufacturers can share scientifically sound and clinically relevant information on unapproved uses with health care providers so long as such presentations are not promotional. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote or advertise any future commercial products will be narrowly limited to those indications that are specifically approved by the FDA.

If we are found to have promoted off-label uses for an FDA-approved drug product, or to have promoted an investigational drug before it has been granted some form of marketing approval, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our other current or future product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we are required by the FDA to obtain approval of a companion diagnostic in connection with approval of any of our product candidates, and we do not obtain, or face delays in obtaining, FDA approval of such companion diagnostic, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. We are working with a diagnostics company to develop a companion diagnostic for firmonertinib to identify patients with EGFR exon 20 insertion mutations and we may be required to pursue a similar approach for EGFR PACC mutations. We may similarly work with diagnostics companies for our other current and any future product candidates. The process of obtaining or creating such diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities, and the FDA has

generally required premarket approval of companion diagnostics for cancer therapies. The approval or clearance of a companion diagnostic as part of the therapeutic product's further labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect.

If the FDA or a comparable foreign regulatory authority requires approval or clearance of a companion diagnostic for any of our product candidates, whether before or after the product candidate obtains marketing approval, we and/or third-party collaborators may encounter difficulties in developing and obtaining approval or clearance for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of the relevant product. For example, our Phase 3 clinical trial of firmonertinib in NSCLC EGFR exon 20 insertion mutations may generate insufficient data to enable the approval by the FDA of the companion diagnostic that we are working with a diagnostics company to develop. If our collaborator is unable to develop and receive marketing authorization for such diagnostic, the approval of firmonertinib could be delayed or prevented and our business would be significantly harmed. We or our collaborators may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidates, if approved, on a timely or profitable basis, if at all.

The commercial success of our current or future product candidates will depend upon the degree of market acceptance of such product candidates by healthcare providers, product recipients, healthcare payors and others in the medical community. If our current or future product candidates fail to achieve the broad degree of adoption by the medical community necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

Even if our current or future product candidates receive regulatory approval, they may not be commercially successful and may not gain market acceptance among healthcare providers, individuals within our target population, healthcare payors or the medical community. The commercial success of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by these individuals and organizations for approved indications. The degree of market acceptance of our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety, including as compared to any more-established products;
- the indications for which our product candidates are approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the establishment of compliant, timely and secure product distribution networks;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as availability, safety and efficacy of competitive drugs;
- the effectiveness of our or any potential future collaborators' sales and marketing strategies; and

- unfavorable publicity relating to the product.

If our current or future product candidates are approved for marketing but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from those products and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

The successful commercialization of our current or future product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our current product candidates, and any future product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Even if we obtain coverage 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.

If we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our products would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions and fines should we be found to be in violation of any applicable obligations thereunder.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available, or at an acceptable level, for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our future products, pricing of existing drugs may limit the amount we will be able to charge for our products. Increasingly, other third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our future products and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative drugs before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our current product candidates and any future product candidates, if approved.

Obtaining and maintaining reimbursement status is time-consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for

products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process 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 applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely.

Additionally, the IRA authorized the CMS to negotiate drug prices annually for a select number of single source Medicare Part D drugs without generic competition starting in payment year 2026, and to negotiate drug prices for a select number of Medicare Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS implemented these new statutory requirements, and has announced lists of Medicare Part D drugs subject to the pricing provisions of the IRA, but their impact on the biopharmaceutical industry in the United States remains uncertain, in part due to several pending federal lawsuits challenging the constitutionality of the program. The outcome of such ongoing lawsuits, as well as potential legislative changes enacted by Congress or programmatic changes implemented at CMS by the Trump Administration, may impact the IRA drug price negotiation program in the future. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize in the future and, if reimbursement is available, what the level of reimbursement will be.

Outside of the United States, international biopharmaceutical sales are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our product candidates, if approved in these jurisdictions. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, if any, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products.

We expect to experience pricing pressures in connection with the sale of any of our product candidates, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs, surgical procedures and other treatments in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Recent federal policy initiatives, including the Trump Administration's "Most Favored Nation" (MFN) drug pricing framework, could materially impact the pricing and commercialization of pharmaceutical products in the United States. The MFN policy seeks to align U.S. drug prices with the lowest prices paid in certain foreign markets, which could result in lower realized prices for innovative therapies and increased pricing pressure at launch. If implemented or expanded, such policies may limit our ability to establish or maintain premium pricing for our products, adversely affect revenue projections, and alter launch sequencing or commercialization strategies. In addition, MFN-based pricing may influence global pricing dynamics, as lower prices established outside the United States could be referenced in U.S. reimbursement determinations, potentially reducing overall global revenue. Ongoing uncertainty regarding the scope, enforcement, and legal durability of MFN-related policies, as well as potential compliance and reporting obligations, may further impact pricing flexibility, market access, and the commercial viability of current and future product candidates. In conjunction with the White House's outreach to individual pharmaceutical companies to seek MFN pricing agreements, the CMS Innovation Center has proposed several drug

pricing demonstration models—referred to as GLOBE, GUARD, and GENEROUS—that are intended to evaluate whether international reference pricing mechanisms and alternative rebate structures can reduce federal drug spending. The outcomes of these upcoming models may materially affect future U.S. drug pricing, reimbursement levels, and market access for pharmaceutical products, including our product candidates, should they be approved for marketing.

We face significant competition, and if our competitors develop and commercialize technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective, safer, or less expensive than our current and any future product candidates we develop, our business and our ability to develop and successfully commercialize products will be adversely affected.

The biopharmaceutical industry is characterized by rapid advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with firmonertinib. Firmonertinib, our other product candidates, and any future product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Our competitors include larger and better-funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities and other research institutions who may be active in research in our target indications and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, and our inability to compete successfully could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing intellectual property related to new product candidates, as well as entering into collaborations, joint ventures, license agreements and other similar arrangements. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We believe that our current and future competition for resources and eventually for customers comes from companies that are commercializing or developing candidates targeting EGFRm-positive NSCLC, including, but not limited to, AstraZeneca, Johnson & Johnson, Blossom Hill Therapeutics, Dizal Pharmaceutical, Oric Pharmaceuticals, Black Diamond Therapeutics, Inc., Cullinan Therapeutics, Inc., Taiho Pharmaceutical Co., Ltd., Boehringer Ingelheim, and Bayer AG. In March 2024 and October 2024, chemotherapy in combination with the anti-EGFR anti-mesenchymal epithelial transition factor receptor bispecific antibody amivantamab was approved in the United States and Europe, respectively, for first line EGFRm NSCLC patients with exon 20 insertion mutations.. In January 2025, Taiho Therapeutics and Cullinan Therapeutics announced that their study of the oral EGFR inhibitor zipalertinib met the primary endpoint in a phase 2b clinical trial of patents in second or later line NSCLC patients with EGFR exon 20 insertion mutations. In July 2025, Dizal Pharmaceutical announced the FDA approval of sunvozertinib in second or later line NSCLC patients with EGFR exon 20 insertion mutations.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for firmonertinib or any other current or future product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competing products may render firmonertinib or any other current or future product candidates we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected. See “Business — Competition.”

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

We have limited commercialization capabilities, nor have we commercialized a product. If our current or future product candidates ultimately receive regulatory approval, we must build a commercial organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate with third parties that have established commercialization systems, either to augment our own commercial organization or in lieu of our own commercial organization. We have no prior experience as a company with the commercializing biopharmaceutical products and there are significant risks involved in the building and managing of a commercial organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to our personnel, monitor compliance on an ongoing basis, and effectively manage a geographically dispersed commercial team. Any failure or delay in the development of our internal commercialization capabilities would adversely impact the commercialization of any future approved products. We compete with many companies that currently have extensive, experienced and well-funded teams to recruit, hire, train and retain commercial personnel, and will have to compete with those companies to recruit, hire, train and retain any of our own commercial personnel. If we are unable to expand our commercial team, we may be unable to compete successfully against these more established companies. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in commercial functions on acceptable financial terms, or at all. In addition, our product revenue and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to commercialize any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to commercialize our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

If the market opportunities for our current or future product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

The precise incidence and prevalence for the various mutations of NSCLC we aim to address with firmonertinib or any other current or future product candidates are unknown. Similarly, the precise incidence and prevalence for the gastrointestinal cancers we aim to address with ARR-217 or any other current or future product candidates are unknown. Our projections of both the number of people who have such cancers or other diseases we target, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on a number of internal and third-party estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of these indications. While we believe our assumptions and the data underlying our estimates are reasonable, we have not independently verified the accuracy of the third-party data on which we have based our assumptions and estimates, and these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, including as a result of factors outside our control, thereby reducing the predictive accuracy of these underlying factors. The total addressable market across all of the potential indications for our current product candidates, and any future product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each such product candidate which receives marketing approval for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of such product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition and results of operations.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize firmonertinib, our other product candidates, and any future product candidates in foreign markets. We are not permitted to market or promote any product candidate before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for firmonertinib or any other current or future product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of firmonertinib, our other product candidates and any future product candidates. Approval procedures may be more onerous than those in the United States and may require that we conduct additional nonclinical studies or clinical trials. If we obtain regulatory approval of product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with export control and import laws and regulations;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- differing regulatory requirements with respect to manufacturing, packaging or distribution of products;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires; and
- disruptions resulting from the impact of public health pandemics or epidemics.

We may not successfully identify, acquire, develop or commercialize new potential product candidates.

Part of our business strategy is to expand our product candidate pipeline by identifying and validating new product candidates, which we may develop ourselves, in-license or otherwise acquire from others. In addition, in the event that our existing product candidates do not receive regulatory approval or are not successfully commercialized, then the success of our business will depend on our ability to expand our product pipeline through internal development, in-licensing or other acquisitions. We may be unable to identify relevant product candidates. If we do identify such product candidates, we may be unable to reach acceptable terms with any third party from which we desire to in-license or acquire them. Any product candidates we identify, acquire, in-license, develop, or manufacture may not be safe or effective for their targeted diseases, and may not receive marketing authorization in a timely manner, or at all.

Risks Related to Our Business Operations and Industry

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to firmonertinib or any other current or future product candidates, which may change from time to time;
- the timing and success or failure of preclinical studies or clinical trials for firmonertinib or other current or any future product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- coverage and reimbursement policies with respect to firmonertinib or any other current or future product candidates, if approved, and potential future drugs that compete with our products;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for any approved products, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies;
- the timing and amount of any milestone, royalty or other payments payable by us or due to us under any collaboration, licensing or other similar agreement; and
- changes in general market and economic conditions.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

We are a clinical-stage company, and, as of December 31, 2025, had 77 full-time employees. We are highly dependent on the research and development, clinical and business development expertise of our executive officers, as well as the other principal members of our management, scientific and clinical team. Although we have entered into offer letters with our executive officers, each of them may terminate his or her employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We will need to develop and expand our organization, and we may encounter difficulties in managing our growth and expanding our operations successfully, which could disrupt our operations.

As of December 31, 2025, we had 77 full-time employees. As we continue development and pursue the potential commercialization of firmonertinib, our other product candidates and any future product candidates, as well as continue to function as a public company, we will need to expand our financial, accounting, development, regulatory, manufacturing, information technology, marketing and sales capabilities or contract with third parties to provide these capabilities for us. We may have difficulty identifying, hiring and integrating new personnel. The expansion of our operations may lead to significant costs and may divert the attention of our management and business development resources away from day-to-day activities and devote a substantial amount of time to managing internal or external growth. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties and we may not be successful in doing so. Our future financial performance and our ability to develop and commercialize firmonertinib, our other product candidates and any future product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

We are subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could expose us to criminal sanctions, civil and administrative penalties, contractual damages, reputational harm and diminished profits and future earnings, among other penalties, any of which could harm our results of operations and financial condition.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from

knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payments Sunshine Act, which requires certain 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 and other "transfers of value" made to physicians, defined to include doctors, dentists, optometrists, podiatrists and chiropractors, certain non-physician practitioners, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and
- some state or local laws that require biotechnology companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; to report information on the pricing of certain drug products; and the registration of pharmaceutical sales representatives doing business within the jurisdiction, among other potentially applicable state and local laws and regulations.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize firmonertinib, our other product candidates, and any future product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any

product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the ACA was enacted in the United States. The ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on the Medicaid drug rebate, set at 100% of a drug's average manufacturing price, beginning January 1, 2024. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for products. Most recently, the IRA introduced a number of significant drug pricing reforms, including the establishment of a drug price negotiation program within the HHS (beginning in 2026) that requires manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation (first due in 2023), and a redesign of the Part D benefit, as part of which manufacturers are required to provide discounts on Part D drugs (beginning in 2025). The program being implemented by HHS is currently the subject of several federal lawsuits, and its ultimate form remains uncertain.

Separately, the Trump Administration announced the creation of a government website called TrumpRx, which will allow consumers to purchase certain drugs at reduced prices as negotiated between the drug manufacturers and the administration. As of January 2026, the Trump Administration had secured deals with 16 major drug manufacturers to offer certain drugs at most-favored-nation prices.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or 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 December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers (PBMs), and other members of the health care and pharmaceutical supply chain, an important decision that had led to further and more aggressive efforts by states in this area. The FTC in mid-2022 also launched sweeping investigations into the practices of the PBM industry, and published interim reports with its findings in mid-2024 and January 2025, that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements, as PBM reform continues to be a bipartisan priority. In February 2026, President Trump signed into law several PBM regulatory reforms as part of a federal budget package, including but not limited to requirements for PBMs to pass back 100% of rebates and fees to commercial health plan sponsors; to provide extensive informational disclosures related to patients' coverage and benefits; and to accept only bona fide service fees from drug companies when providing services under Medicare Part D. The Department of Labor (DOL) also issued a proposed rule in January 2026 that would mandate specific PBM fee disclosures to self-insured plan fiduciaries under ERISA. If finalized as proposed, the DOL rule would also allow plan fiduciaries to audit those PBM disclosures to confirm accuracy. Additional proposals and legislative changes aimed at PBMs and their business practices are likely to continue to be introduced and considered in Congress and by executive agencies. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including innovative drug product developers like us.

Legally mandated price controls on payment amounts by third-party payors or other restrictions, if enacted and applicable to any of our future commercial products, could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare 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 healthcare programs. This could reduce the ultimate demand for firmonertinib, our other product candidates, and any future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We expect that these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize firmonertinib, our other product candidates and any future product candidates, if approved.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit, delay or cease commercialization of any products we may develop.

We face an inherent risk of product liability as a result of the clinical trials of firmonertinib, our other product candidates, and any future product candidates and will face an even greater risk if we commercialize our product candidates, especially if our products are prescribed for off-label uses, even though we do not promote such uses. For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit, delay or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our future products;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of our management's time and our resources;
- substantial monetary awards to any injured patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize firmonertinib or any other current or future product candidates; and
- a decline in our stock price.

We currently hold approximately $10.0 million in product liability insurance coverage in the aggregate. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of firmonertinib or any other current or future product candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential

product liability claims could prevent or inhibit the commercialization of firmonertinib or any other current or future product candidates. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employment benefits liability, workers' compensation, products liability, malicious invasion of our electronic systems, and directors' and officers', and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

We are subject to complex and evolving U.S. and foreign laws, regulations, and rules, as well as contractual obligations, and policies related to data privacy and data protection. Our, or those of collaborators or other third parties on which we rely, actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we collect and process personal data and other sensitive information, including proprietary and confidential business data, trade secrets, employee data, intellectual property, data we collect about trial participants in connection with clinical trials, and other sensitive third-party data. Our data processing activities may subject us to numerous privacy and data protection obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to privacy and data protection.

Various federal, state, local and foreign legislative and regulatory bodies, or self-regulatory organizations, may expand or amend current laws, rules or regulations, enact new laws, rules or regulations or issue revised rules or guidance regarding privacy and data protection. In the United States, federal, state, and local governments have enacted numerous privacy and data protection laws, including data breach notification laws, personal data privacy laws, consumer protection laws, e.g., Section 5 of the Federal Trade Commission Act, and other similar laws, e.g., wiretapping laws. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations (collectively, HIPAA), imposes certain privacy and security requirements for individually identifiable health information on certain entities, namely certain healthcare providers, health plans, and healthcare clearinghouses (covered entities) and their respective "business associates" who directly or as a subcontractor provide services involving the creation, use, maintenance or disclosure of individually identifiable health information on covered entities' behalf. As a clinical trial sponsor, we are not directly subject to HIPAA, but we do have relationships with providers and other entities subject to the law and thus must structure those relationships in a manner consistent with HIPAA requirements. If any of the physicians or other health care providers or entities with whom we expect to do business are found to be not in compliance with HIPAA or other applicable privacy laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs. If regulatory authorities challenge our activities, or those of a collaborator or other third party on which we rely, under HIPAA or other privacy laws applicable to the privacy and security of health information, any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any investigation of or enforcement against us or the third parties with whom we contract, including a research collaborator, regardless of the outcome, would be costly and time consuming, and may negatively affect our ability to conduct clinical trials, results of operations and financial condition.

Other federal and state laws establish additional requirements for protecting the privacy and security of health information that is not protected by HIPAA. For instance, Washington state recently passed the "My Health My Data" Act, which came into force in 2024 and regulates "consumer health data," which is defined as "personal information that is linked or reasonably linkable to a consumer and that identifies a consumer's past, present, or future physical or mental health." The "My Health My Data" Act provides exemptions for personal data used or shared in connection with certain research activities, including data subject to 45 C.F.R. Parts 46, 50 and 56. Notably, the "My Health My Data" Act contains a private right of action. In addition, Nevada recently enacted a consumer health data privacy bill, SB 370, which also took effect in 2024, and regulates "consumer health data." SB 370 shares many similarities with Washington's "My Health My Data" Act, and Connecticut recently amended its comprehensive privacy law to include heighted regulation of "consumer health data." Additional states may adopt health-specific privacy laws that could impact our business activities and our collection and handling of health-related data.

More broadly, various U.S. states now regulate the processing of personal data. For example, California was the first of an ever-increasing number of states to enact comprehensive state privacy legislation with the California Consumer Privacy Act (CCPA), which went into effect in January of 2020. The CCPA established a privacy framework for covered businesses by creating an expanded definition of personal data, establishing data privacy rights for California residents, requiring covered businesses to provide disclosures to California residents, and creating a statutory damages framework with the potential for severe damages for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches, as well as a private right of action for certain data breaches. Additionally, in 2020 California voters passed the California Privacy Rights Act of 2020 (CPRA), which went into effect on January 1, 2023. The CPRA significantly amends and expands the CCPA, such as granting additional rights to California residents, including the right to correct personal data and additional opt-out rights. Among other things, the CPRA also establishes a regulatory agency, the California Privacy Protection Agency, which enacts new regulations under the CCPA and has expanded enforcement authority. In 2023, comprehensive privacy laws in Virginia, Colorado, Connecticut, and Utah all took effect, and laws in Montana, Oregon, and Texas took effect during 2024. Laws in a number of other U.S. states took effect, or are set to take effect, in 2025, in 2026, and beyond. Additional U.S. states have proposals under consideration, all of which are likely to increase our regulatory compliance costs and risks, exposure to regulatory enforcement action, and other liabilities. While these state privacy laws, such as the CCPA, contain exemptions for certain types of personal data, such as personal data processed in the context of clinical trials, these laws may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. The scope and enforcement of these laws is uncertain and evolving. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self-regulatory standards that may place additional burdens on us.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal data as well. In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries and may be subject to the General Data Protection Regulation (GDPR) and UK GDPR, as well as other foreign data protection laws. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries and impose other restrictions on processing sensitive personal data, including genetic information and testing information. In particular, the EEA and the United Kingdom have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. In July 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring personal data from the European Union to the United States, the EU-U.S. Data Privacy Framework, which provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. In addition, the EU-U.S. Data Privacy Framework offers additional redress avenues for violations, including free of charge independent dispute resolution mechanisms and an arbitration panel. The United Kingdom followed the European Commission in October of 2023 and adopted its "extension" to the EU-U.S. Data Privacy Framework. The European Commission and the United Kingdom will continually review developments in the United States along with their adequacy decisions. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. Future actions of EU and UK data protection authorities are difficult to predict, and the GDPR permits EU states to frame national legislation that may derogate from the GDPR.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Regulators in the United States such as the Department of Justice are also increasingly scrutinizing certain personal data transfers and, effective October of 2025, the DOJ has implemented what is known as the Bulk Transfer Rule restricting transfers of bulk sensitive personal data (like health, genomic, or financial info) and U.S. government-related data to "countries of concern" (e.g., China, Russia) or related entities, focusing on national security by preventing adversary access, absent an exception that permits such transfers. It requires U.S. companies to implement data security programs, audit compliance, and maintain records, with significant penalties for violations, aiming to safeguard sensitive U.S. data from foreign adversaries. In the ordinary course of business, as part of our clinical development programs, we transfer health and other data to China and we could face significant adverse consequences, including the interruption or degradation of our operations at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business if we are unable to comply with the requirements of the Bulk Transfer Rule.

In addition to privacy and data protection laws in the United States, European Union, and United Kingdom, various other jurisdictions in which we operate have established legal frameworks relating to privacy, data protection, and information security matters to which we may also be subject. For example, we are also subject to laws in China. Under the Cybersecurity Law of the People's Republic of China (China's Cybersecurity Law), any collection, use, transfer and storage of personal information of a Chinese citizen through a network by the network operator should be based on the three principles of legitimacy, justification and necessity and requires the consent of the data subject. The rules, purposes, methods and ranges of such collection should also be disclosed to the data subject. China's data localization requirements are becoming increasingly common in sector-specific regulations, and laws including data localization requirements exist in many of the other jurisdictions in which we operate. For example, China's Cybersecurity Law requires operators of critical information infrastructure (CIIOs) to store personal information and important data collected and generated from the critical information infrastructure within China. Non-compliance with China's Cybersecurity Law can result in fines for the relevant entity as well as for the personnel directly responsible. On September 14, 2022, the Cyberspace Administration of China (CAC), China's top cybersecurity regulator, released new amendments to China's Cybersecurity Law for public consultation and if the amendments are passed, the amended law will increase the penalties for violations of cybersecurity obligations under the Cybersecurity Law to up to RMB 50 million, in line with those under the Data Security Law and PIPL.

Building on this, China's Data Security Law (Data Security Law) became effective on September 1, 2021. The primary purpose of the Data Security Law is to regulate data activities, safeguard data security, promote data development and usage, protect individuals and entities' legitimate rights and interests, and safeguard state sovereignty, state security and development interests. The Data Security Law applies extraterritorially, and to a broad range of activities that involve "data" (not only personal or sensitive data). Under the Data Security Law, entities and individuals carrying out data activities must abide by various data security obligations. For example, the Data Security Law proposes to classify and protect data based on the importance of data to the state's economic development, as well as the degree of harm it will cause to national security, public interests, or legitimate rights and interests of individuals or organizations when such data is tampered with, destroyed, leaked, or illegally acquired or used. The appropriate level of protective measures is required to be taken for each respective class of data. The Data Security Law also echoes the data localization requirement in the Cybersecurity Law and requires important data to be stored locally in China. Such important data may only be transferred outside of China subject to compliance with certain data transfer restrictions, such as passing a security assessment organized by the relevant authorities.

The Cybersecurity Review Measures, which took effect on February 15, 2022 in China, clarify when entities must apply for a mandatory cybersecurity review from the Chinese government authorities. These circumstances include (i) when CIIOs purchase network products that may affect national security, (ii) when a network platform operator's data processing activities may affect national security, or (iii) when a network platform operator holds personal information of more than one million individuals and plans on listing publicly outside China. Network platform operators are not defined under the Cybersecurity Review Measures but are understood to be broadly interpreted to include all Internet platform operators or service providers, thus providing for a broad application. A mandatory cybersecurity review is likely to prolong the timeline of any contemplated listing timeline outside China and increase the regulatory compliance burden on entities that are subject to this requirement. At this time, the Company does not act as a network platform operator and does not hold the personal information of more than one million individuals in China, and as such, we do not believe the Company would be subject to the Cybersecurity Review Measures. However, the relevant Chinese authorities have great discretion, and it is generally uncertain as to how they may interpret and enforce the Cybersecurity Review Measures in practice.

Additionally, on August 20, 2021, China announced the Personal Information Protection Law (PIPL), which took effect on November 1, 2021. The PIPL is intended to clarify the scope of application, the definitions of personal information and sensitive personal information, the legality of personal information processing and the basic requirements of notice and consent, among other things. The PIPL also sets out data localization requirements for CIIOs and personal information processors who process personal information above a certain threshold prescribed by the relevant authorities. The PIPL also includes a list of rules which must be complied with prior to the transfer of personal information outside of China, such as compliance with a security assessment or certification by an agency designated by the relevant authorities or entering into standard form model contracts approved by the relevant authorities with the overseas recipient.

On July 7, 2022, the CAC issued Security Assessment Measures for Outbound Data Transfers, which became effective on September 1, 2022. The Security Assessment Measures for Outbound Data Transfers clarifies the security assessment requirement under the PIPL and requires a data processor to apply for the security assessment organized by the CAC under any of the following circumstances before the information is transferred outbound: (i) where a data processor provides key data overseas, (ii) critical information infrastructure operator and personal information processors who process more than one million individuals' personal information; (iii) where a data processor has cumulatively provided personal information of over 100,000 individuals or sensitive personal information of over 10,000 individuals in total abroad since January 1st of the previous year. Additionally, on November 18, 2022, the CAC and the State Administration of Market Regulation issued the Implementation Rules for Personal Information Protection Certification which apply with immediate effect and which provide important guidance on obtaining a personal information certification for lawful cross-border transfer of personal information under the PIPL.

Notably, the PIPL, similar to both the GDPR and certain U.S. privacy laws, applies extraterritorially. Failure to comply with PIPL can result in fines of up to RMB 50 million or 5% of the prior year's total annual revenue for the personal information processor and/or a suspension of services or data processing activities. Other potential penalties include a fine of up to RMB 1 million on the person in charge or directly responsible personnel and, in serious cases, individuals and entities may be exposed to criminal liabilities under other local Chinese law, such as the Criminal Law of the People's Republic of China. The PIPL also prohibits responsible personnel for violations of the PIPL from holding high level management or data protection officer positions in relevant enterprises.

In addition to China's Cybersecurity Law, the Data Security Law and the PIPL, the government agencies of China promulgated several regulations or released a number of draft regulations for public comments which are designed to provide further implemental guidance in accordance with the laws mentioned above. We cannot predict what impact the new laws and regulations or the increased costs of compliance, if any, will have on our operations in China, in particular the Data Security Law or PIPL, or the increased costs of compliance, if any, will have on our operations in China due to their recent enactment and the limited guidance available on their scope and applicability, particularly on PIPL. It is also generally unclear how the laws will be interpreted and enforced in practice by the relevant government authorities as often the abovementioned laws are drafted broadly and thus leaves great discretion to the relevant government authorities to exercise.

We also publicly post privacy policies and notices that describe our practices concerning our collection, use, disclosure and other processing of personal data. Although we endeavor to comply with our public-facing privacy policies and notices, we may at times fail to do so or be perceived to have failed to do so, and we may be subject us to enforcement actions if our privacy policies and notices are found to be deceptive, unfair or misrepresentative of our actual practices, which could result in, regulatory inquiries and investigations or adverse publicity and could cause our customers and collaborators to lose trust in us, any of which could adversely affect our business, financial condition, results of operations and prospects.

Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, the Company may find that it is violating the laws or regulations of another jurisdiction. Despite the Company's efforts, the Company may not have fully complied in the past and may not in the future. Evolving legal, contractual, and other privacy and data protection obligations, could impose significant limitations, require changes to our business, or restrict our collection, use, storage or processing of personal data, which may increase our compliance expenses and make our business more costly or less efficient to conduct. In addition, any such changes could impact our ability to develop an adequate marketing strategy and pursue our growth strategy effectively, or even prevent us from providing certain products in jurisdictions in which we currently operate, and in which we may operate in the future, or incur potential liability in an effort to comply, which, in turn, could adversely affect our business, financial condition, results of operations and prospects. Complying with these numerous, complex and often evolving requirements is expensive and difficult, and suspected and actual failure to comply, whether by us, our service providers, CROs, business partners or other third parties, or any inadvertent or unauthorized access to or use or disclosure of data that we store or handle as part of operating our business, could adversely affect our business, financial condition, results of operations and prospects, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limit our ability to develop or commercialize our products; expenditure of time and resources; investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief. We may also be contractually required to indemnify and hold harmless third parties.

The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

If our internal information technology systems, or those used by our CROs, clinical sites, or other contractors or consultants upon which we rely, are or were compromised, become unavailable or suffer cybersecurity incidents, loss or leakage of data or other disruptions, we could suffer material adverse consequences resulting from such compromise, including but not limited to, operational or service interruption, harm to our reputation, litigation, fines, penalties and liability, compromise of sensitive information related our business, and other adverse consequences.

In the ordinary course of our business, we, and the third parties upon which we rely, process sensitive data and as a result, we and the third parties upon which we rely face a variety of evolving threats which could cause cybersecurity incidents.

Despite our implementation of security measures, our internal information technology systems and those of our CROs, clinical sites, and other contractors and consultants upon which we rely are vulnerable to cyberattacks, computer viruses, bugs, worms, or other malicious codes, malware, including as a result of advanced persistent threat intrusions, and other attacks by computer hackers, cracking, application security attacks, social engineering, including through phishing attacks, supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks, such as credential stuffing, credential harvesting, personnel misconduct or error, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Finally, developments in artificial

intelligence (AI) and machine learning provide threat actors with the capability to use more sophisticated means to attack our systems and may exacerbate cybersecurity risk. There can be no assurance that we will be successful in preventing cybersecurity incidents or successfully mitigating their effects.

Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel, such as through theft or misuse, sophisticated nation states, and nation-state-supported actors. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data, including sensitive customer information, loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the negative impact of a ransomware attack, it may be preferable to make payments to the threat actors, but we may be unwilling or unable to do so, including, for example, if applicable laws or regulations prohibit such payments.

Some threat actors also now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors, for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain and ability to produce, sell and distribute our goods and services. In addition to experiencing a cybersecurity incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Additionally, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

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

While we take steps to detect and remediate vulnerabilities, we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit such vulnerabilities change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a cybersecurity incident has occurred, if at all. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. We also rely on third-party service providers to assist with our clinical trials, provide other products or services, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a cybersecurity incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems, including our services, or the third-party information technology systems that support us and our services.

Any of the previously identified or similar threats could cause a cybersecurity incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A cybersecurity incident or other interruption could disrupt our ability, and that of third parties upon whom we rely, to provide our products and services and conduct clinical trials.

The costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses. If the information technology systems of our CROs, clinical sites, and other contractors and consultants become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

If any such incidents were to occur and cause interruptions in our operations, it could result in a disruption of our business and development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data or may limit our ability to effectively execute a product recall, if required in the future. To the extent that any disruption or cybersecurity incident were to result in the loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any product candidates could be delayed. Applicable data privacy and security obligations may require us to notify relevant stakeholders, regulatory authorities and other individuals of cybersecurity incidents, and take other remedial measures. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Any such event could also result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates.

Our business, operations and clinical development timelines and plans are subject to risks arising from epidemic or pandemic diseases.

Our business, financial condition, and results of operations could be adversely affected by public health threats, including epidemics and pandemics, that disrupt our commercial operations, supply chains, clinical trials, and other essential activities.COVID-19, which is no longer considered a public health emergency both globally and in the United States, presented substantial public health and economic challenges and affected our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. During the COVID-19 pandemic, international and U.S. governmental authorities in impacted regions took multiple and diverse actions in an effort to slow the spread of COVID-19 and variants of the virus, including issuing varying forms of “stay-at-home” orders. Such measures taken by the governmental authorities to respond to any future epidemic or pandemic disease outbreaks could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for firmonertinib and our other product candidates for use in our clinical trials and research and nonclinical studies and, delay, limit or prevent our employees and CROs from continuing research and development activities, impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, including due to measures taken that may limit social interaction or prevent reopening of high-transmission settings, impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our nonclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. Any future epidemic or pandemic disease outbreak could also potentially further affect the business of the FDA, the European Medicines Agency (EMA) or other comparable regulatory authorities, which could result in delays in meetings related to our planned clinical trials. Any future epidemic disease outbreak may have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed.

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

In some countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low-priced and high-priced countries, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies, which is time-consuming and costly. If coverage and reimbursement of our product candidates are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings which may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations. Even if such a proceeding, investigation or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources.

Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could harm our business, financial condition and results of operations.

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other similar foreign regulatory authority requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad (iv) laws that require the true, complete and accurate reporting of financial information or data, or (v) laws that prohibit insider trading. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may engage in strategic transactions that could increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, subject us to other risks, adversely affect our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits. Furthermore, we may experience losses related to investments in other companies, including as a result of failure to realize expected benefits or the materialization of unexpected liabilities or risks, which could have a material negative effect on our results of operations and financial condition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our ability to use net operating loss carryforwards and other tax attributes may be limited in connection our initial public offering completed in January 2024 or other ownership changes.

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, subject to limitations, until such unused losses expire, if at all. At December 31, 2025, we had gross net operating loss (NOL) carryforwards of $138.5 million for federal income tax purposes and $121.7 million for state income tax purposes. Our federal NOL carryforwards will not expire but may generally only be used to offset 80% of taxable income, which may require us to pay federal income taxes in future years despite generating federal NOL carryforwards in prior years. We also had research and development tax credit carryforwards of $9.1 million that will begin to expire in 2041.

In addition, our NOL carryforwards and other tax attributes are subject to review and possible adjustment by the Internal Revenue Service (IRS) and state tax authorities. Furthermore, in general, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the Code), our federal and state NOL carryforwards and research and development tax credit carryforwards may be or become subject to an annual limitation in the event we have had or have in the future an "ownership change." For these purposes, an "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We have not yet determined the amount of the cumulative change in our ownership resulting from our initial public offering completed in January 2024 or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. However, we believe that our ability to utilize our NOL carryforwards and

other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes including changes related to our initial public offering completed in January 2024. If we earn taxable income, such limitations could result in increased future income tax liability to us and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOL and credit carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

New tax legislation may impact our results of operations and financial condition.

The IRA introduced, among other changes, a 15% corporate minimum tax on certain United States corporations and a 1% excise tax on certain stock redemptions by United States corporations. The U.S. government may enact further significant changes to the taxation of business entities. The likelihood of these changes being enacted or implemented is unclear. We are currently unable to predict the ultimate impact of the IRA or any such further changes on our business.

Inflation could adversely affect our business and results of operations.

While inflation in the United States has been relatively low in recent years, from 2021 to 2023, the economy in the United States encountered a material level of inflation. Inflation and fluctuations in inflation rates have had in the past, and may in the future have, negative effects on economies and financial markets, particularly in emerging economies. For example, increases in inflation raise our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Governmental efforts to curb inflation often have negative effects on the level of economic activity. There can be no assurance that inflation will not become a serious problem in the future and have an adverse impact on the Company's returns. The geopolitical developments such as the Russia-Ukraine and Middle East conflicts and global supply chain disruptions continue to increase uncertainty in the outlook of near-term and long-term economic activity, as well as the interest rate environment, which may make it more difficult, costly or dilutive for us to secure additional financing. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations or cash flows.

In light of the presidential transition in 2025, global trade disputes may be magnified, including the continuing trade dispute between the United States and China, pursuant to which both countries have, among other things, imposed tariffs on one another, has had an adverse economic effect on U.S. markets and international trade more broadly. This adverse economic effect is likely to become more pronounced if the dispute remains unresolved, which could have a material adverse impact on our financial condition, results of operations or cash flows.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain, sufficient intellectual property protection for firmonertinib, our other product candidates or future product candidates or technology, or if the scope of our intellectual property rights is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize firmonertinib or any other current or future product candidates may be adversely affected.

Our commercial success depends in large part on our ability to obtain, maintain, enforce, and defend patent rights, trademarks and our proprietary know-how of sufficient scope in the United States and other countries with respect to our product candidates and other proprietary technologies we may develop. If we are unable to obtain, maintain or enforce our intellectual property rights of sufficient scope, our business, financial condition, results of operations and prospects could be materially harmed.

We rely on in-licensed patent rights for our current product candidates. Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our or our licensor’s ability to protect our intellectual property, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the patents we have in-licensed will provide sufficient protection against competitors or other third parties, or if these patents are challenged by our competitors, will be found to be invalid, unenforceable, or not infringed. We also cannot predict

whether patent application our licensor is currently pursuing or patent application we may in the future pursue or in-license will issue as patents in any particular jurisdiction.

The patent prosecution process is expensive, time-consuming, and complex, and we or our licensors may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications or reissue applications at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection before public disclosures are made. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, third-party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our or our licensors' ability to seek patent protection. Consequently, we may not be able to prevent any third party from using any of our technology that is in the public domain to compete with our current product candidates, and any future product candidates or technologies. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable in light of the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to invent the inventions claimed in any of our licensed patents or pending patent applications, or that we or our licensors were the first to make the inventions claimed in those owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patents and patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable.

Composition of matter patents for pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims covering compositions of matter in any of our issued or reissued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued. Any issued patents may not afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates. Further, even if these patents are granted, they may be difficult to enforce. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. In the event we experience noncompliance events that cannot be corrected and we lose our patent rights, competitors could enter the market, which would have a material adverse effect on our business. Further, any issued patents that we license or may license or own covering our firmonertinib or any other current or future product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or other countries, including the United States Patent and Trademark Office (USPTO). Also, patent terms, including any extensions or adjustments that may or may not be available to us, may be inadequate to protect our competitive position on our product candidates for an adequate amount of time, and we may be subject to claims challenging the inventorship, validity, or enforceability of our patents and/or other intellectual property. Changes in United States patent law, or laws in other countries, could diminish the

value of patents in general, thereby impairing our ability to protect our product candidates. Further, if we encounter delays in our clinical trials or delays in obtaining regulatory approval, the period of time during which we could market our product candidates under patent protection would be reduced. Thus, the patents that we own and license may not afford us any meaningful competitive advantage.

Moreover, the claim coverage in a patent application can be significantly narrowed before the corresponding patent is granted. Even if our owned or in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents issuing from our patent applications may be challenged, narrowed, circumvented or invalidated by third parties. Our competitors or other third parties may avail themselves of safe harbors under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) to conduct research and clinical trials. Consequently, we do not know whether firmonertinib or any of our other current or future product candidates and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. In addition, given the amount of time required for the development, testing and regulatory review of our current and future product candidates, patents protecting the product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability and our patent rights may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party post-issuance submission of prior art to the USPTO challenging the validity of one or more claims of our in-licensed patents or patents we may own in the future. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. A third party may also claim that our patent rights are invalid or unenforceable in litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In addition, we may become involved in opposition, derivation, revocation, reexamination, reissue, post-grant and inter partes review or interference proceedings and other similar proceedings in foreign jurisdictions challenging the validity, priority or other features of patentability of our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and other proprietary technologies we may develop and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our products without infringing third-party patent rights. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing, could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, some of our patent rights are, and may in the future be, co-owned with third parties, including Allist. In the United States, each co-owner has the freedom to license and exploit the technology. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patent rights, such co-owners may be able to license their rights to other third parties without our consent, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of such patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We depend heavily on intellectual property licensed from third parties, and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

We are a party to the Allist License Agreement, the Amended and Restated Aarvik Collaboration Agreement and the Lepu Biopharma Agreement (collectively, License Agreements) under which we are granted rights to intellectual

property that are critical to our product candidates and our business and we may enter into additional license agreements in the future with other third parties. The License Agreements impose, and we expect that any future license agreements where we in-license intellectual property, will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. We may need to devote substantial time and attention to ensuring that we are compliant with our obligations under such agreements, which may divert management's time and attention away from our research and development programs or other day-to-day activities. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license, or we may be subject to litigation for breach of these agreements.

If we or our licensors fail to adequately prosecute, maintain and protect our licensed intellectual property, our ability to commercialize our current or any future product candidates could suffer. We do not have complete control over the maintenance, prosecution and litigation of our in-licensed patents and patent applications and may have limited control over future intellectual property that may be in-licensed. For example, we cannot be certain that activities such as the maintenance and prosecution by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. It is possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant patents, know-how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes that may arise between us and our licensors regarding intellectual property subject to a license agreement could include disputes regarding:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our current or any future product candidates and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected technology or our current product candidates or any future product candidates. As a result, any termination of or disputes over our intellectual property licenses could result in the loss of our ability to develop and commercialize our current product candidates or any future product candidates, or we could lose other significant rights, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Filing, prosecuting, maintaining, enforcing and defending patents covering or relating to our current product candidates and any future product candidates in all countries throughout the world is expensive, and the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Prosecution of patent applications is often a longer process and patents may grant at a later date, and with a shorter term, than in the United States. The requirements for patentability differ in certain jurisdictions and countries. Additionally, the patent laws of some countries do not afford intellectual property protection to the same extent as the laws of the United States. For example, unlike patent law in the United States, patent law in most European countries and many other jurisdictions

precludes the patentability of methods of treatment and diagnosis of the human body. Other countries may impose substantial restrictions on the scope of claims, limiting patent protection to specifically disclosed embodiments. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, or from selling or importing products made using our intellectual property in and into the United States or other jurisdictions. Competitors may use our or our licensors' intellectual property in jurisdictions where we or our licensors have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our owned and in-licensed patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan and China, may have a higher standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

In addition, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some circumstances, we are dependent

on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. For example, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications or any patents and applications we may own in the future. In certain circumstances, we rely on our licensors to pay these fees due to U.S. and non-U.S. patent agencies. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The USPTO and various non-U.S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the United States, China, India and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (e.g., items related to national security or national defense). In some cases, a foreign filing license may be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We are also dependent on our licensors to take the necessary actions to comply with these requirements with respect to our licensed intellectual property.

Changes in patent laws or their interpretations could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the America Invents Act) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Since March 2013, a third party that files a patent application in the USPTO, but before us or our licensors could be awarded a patent covering an invention of ours or our licensors even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our current product candidates or any of our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also included a number of significant changes that affected the way patent applications are prosecuted and also affect patent litigation. These include allowing third party protests and submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation increased the uncertainties and costs

surrounding the prosecution of our patent applications and the enforcement or defense of patents issuing from those patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. We cannot predict how decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

In addition, in 2012, the European Union Patent Package (EU Patent Package) regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (UPC) for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the European Patent Package, now by default automatically fall under the jurisdiction of the UPC. The UPC provides third parties, including our competitors, with a new forum to seek to centrally revoke our European patents and to seek to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the current EU Patent Package, we have the right to opt our patents out of the UPC for the first seven years of the UPC's existence, but doing so may preclude us from realizing the benefits of this new unified court.

Issued patents covering our current product candidates or our future product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Our patent rights may be subject to priority, validity, inventorship and enforceability disputes. Legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time-consuming and likely to divert significant resources from our core business, including distracting our management and scientific personnel from their normal responsibilities and generally harm our business. If we or our licensors are unsuccessful in any of these proceedings, such patents and patent applications may be narrowed, invalidated or held unenforceable, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or we may be required to cease the development, manufacture and commercialization of our current product candidates or future product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we or our licensors initiate legal proceedings against a third party to enforce a patent covering our current product candidates or any of our future product candidates, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, lack of sufficient written description, failure to claim patent-eligible subject matter or obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patent rights in such a way that they no longer cover our product candidates or prevent third parties from competing with our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity

question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our current product candidates and any future product candidates. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that our patents will not be challenged and rendered invalid and/or unenforceable.

We have pending in-licensed patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own, or in-license will result in issued patents with claims that cover our current product candidates or any of our future product candidates or uses thereof in the United States or in other foreign countries.

The claims in our pending patent applications directed to our current product candidates and any of our future product candidates and/or technologies may not be considered patentable by the USPTO or by patent offices in foreign countries. Any such patent applications may not issue as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, the claims in any of our issued patents may not be considered valid by courts in the United States or foreign countries.

Patent terms may be inadequate to protect the competitive position of our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent has expired, we may be vulnerable to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not have

sufficient patent life to protect our products, our business, financial condition, results of operations, and prospects will be adversely affected.

If we do not obtain patent term extension in the United States and equivalent extensions outside of the United States for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of our current product candidates or future product candidate we may develop, one or more of our in-licensed issued U.S. patents or issued U.S. patents we may own in the future may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A 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 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 patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate. However, we may not be granted an extension for various reasons, including failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or failing to satisfy other applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third-party, we may need the cooperation of that third party. If we are unable to obtain patent term extension, or the foreign equivalent, or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

We or our licensors may be subject to claims that former employees, consultants, collaborators or other third parties have an interest in our patent rights, any potential trade secrets, or other intellectual property as an inventor, co-inventor or owner of any potential trade secrets. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, any potential trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we or our licensors have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products and product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover product candidates or the use of our product candidates. The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products.

We may incorrectly determine that our products or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid and unenforceable. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Third-party claims of intellectual property infringement, misappropriation or other violations against us or our collaborators could be expensive and time consuming and may prevent or delay the development and commercialization of our product candidates.

Our commercial success depends in part on our ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products and techniques without payment, or limit the duration of the patent protection of our technology. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including inter partes review and post-grant review have also been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patent rights in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we plan to commercialize our current product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our current product candidates or any future product candidates, and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot assure you that our current product candidates or any future product candidates will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued for which a third party, such as a competitor in the fields in which we are developing our current product candidates or our future product candidates, might accuse us of infringing. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to our current product candidates and any future product candidates. As such, we monitor third-party patents in the relevant pharmaceutical markets. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe.

In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by us. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Such licenses may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms or at all, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. In addition, we may in the future pursue patent challenges with respect to third-party patents, including as a defense against the foregoing infringement claims. The outcome of such challenges is unpredictable.

Even if resolved in our favor, the foregoing proceedings could be very expensive, particularly for a company of our size, and time-consuming. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Such proceedings may also absorb significant time of our technical and management personnel and distract them from their normal responsibilities. Uncertainties resulting from such proceedings could impair our ability to compete in the marketplace. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

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

Third parties, such as a competitor, may infringe our patent rights. In an infringement proceeding, a court may decide that a patent owned by us or licensed to us is invalid or unenforceable or may refuse to stop the other party from using the invention at issue on the grounds that the patent does not cover the technology in question. In addition, our or our licensors' patent rights may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time-consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and proceedings, there is a risk that some of our confidential information could be compromised by disclosure during such litigation and proceedings.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing, misappropriating or violating other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in the markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we may propose to use with our current product candidates or any future product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe, misappropriate or otherwise violate the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to obtain, protect or enforce our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement, misappropriation, dilution or other claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to obtain, enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights to technology for our development pipeline through acquisitions and in-licenses.

The growth of our business may depend in part on our ability to acquire, in-license or use third-party intellectual property and proprietary rights. For example, our current product candidates or any future product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing our compounds and pre-existing pharmaceutical compounds, or we may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patent or other intellectual property rights we may co-own with third parties, we may require licenses to such co-owners' interest to such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe, misappropriate or otherwise violate those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive,

which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we may collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our current product candidates or any future product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business financial condition, results of operations and prospects could suffer.

Our intellectual property licensed from third parties may be subject to retained rights.

Our current or future licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. For example, pursuant to the Allist License Agreement, Allist retains its rights for any and all purposes in certain retained territories regarding its patent rights, improvements and know-how related to any product containing firmonertinib or any of its derivatives as an active ingredient, including to research, develop, make, have made, use, sell, have sold, offer for sale, import, export and license products and processes in such retained territory. Similar provisions are contained in the other license agreements. It is difficult to monitor whether our licensors will limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

Government agencies may provide funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may have retained rights in such intellectual property. For example, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (the Bayh-Dole Act); these include the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize licensed products. While it is our policy to avoid engaging any potential university partners in projects in which there is a risk that government funds may be commingled, we cannot be sure that any such co-developed intellectual property will be free from government rights. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with government funds subject to certain government rights, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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

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

Should any of the foregoing occur, it could adversely affect our business, financial condition, results of operations and prospects.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Some of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may

bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Because we currently rely on, or expect to rely on, third parties to manufacture our current product candidates and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including potential trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including any potential trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and despite our efforts to protect any potential trade secrets, a competitor's or other third party's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure of such technology or information would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of any potential trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for our product candidates and proprietary technologies, we may also rely on trade secret protection and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. We seek to protect any potential trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, third-party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Trade secrets and know-how can be difficult to protect. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. We cannot guarantee that we have entered into applicable agreements with each party that may have or have had access to any potential trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including any potential trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that any potential trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to any potential trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our potential trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us.

Furthermore, others may independently discover any potential trade secrets and proprietary information. If any of our potential trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our potential trade secrets were to be disclosed or misappropriated or if any such information were to be independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that third parties have an ownership interest in any potential trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing our product candidate. Litigation may be necessary to defend against these and other claims challenging ownership of any potential trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our product candidates and other proprietary technologies we may develop. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Common Stock

An active, liquid and orderly market for our common stock may not develop, or we may in the future fail to satisfy the continued listing requirements of Nasdaq and our stock may be delisted, and you may not be able to resell your common stock at your purchase price or at all.

Our common stock only recently began trading on the Nasdaq Global Market, and we can provide no assurance that we will be able to develop an active trading market for our common stock. Even if an active trading market is developed, it may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

The trading price of our common stock is likely to be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and others, including:

- results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- our ability to enroll subjects in our future clinical trials;
- our ability to obtain and maintain regulatory approval of our current product candidates or any future product candidates or additional indications thereof, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory or legal developments in the United States and foreign countries, particularly in China;
- changes in the structure of healthcare payment systems;
- the success or failure of our efforts to identify, develop, acquire or license additional product candidates;
- innovations, clinical trial results, product approvals and other developments by our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

- the degree and rate of physician and market adoption of any of our current and future product candidates;
- manufacturing, supply or distribution delays or shortages, including our inability to obtain adequate product supply, at acceptable prices or at all;
- any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us, including variations from expectations of securities analysts or investors;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding or obtaining funding on unattractive terms;
- sales of our stock by us, our insiders or our stockholders,;
- general economic, industry and market conditions other events or factors, many of which are beyond our control;
- actual or anticipated fluctuations in our financial condition and results of operations;
- publication of news releases by our partners, other companies in our industry, and especially direct competitors, including about adverse developments related to safety, effectiveness, accuracy and usability of their products, reputational concerns, reimbursement coverage, regulatory compliance, and product recalls;
- announcement or progression of geopolitical events, including in relation to the conflicts in the Middle East and between Russia and Ukraine;
- additions or departures of senior management or key personnel;
- intellectual property, product liability or other litigation against us or our inability to enforce our intellectual property;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their common stock and may otherwise negatively affect the liquidity of the trading market for our common stock.

In addition, the stock market has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval and may prevent new investors from influencing significant corporate decisions.

As of February 27, 2026, our executive officers, directors and greater than 5% stockholders, in the aggregate, own a substantial portion of our outstanding common stock. As a result, such persons, acting together, have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the

appointment of our management, the election and removal of directors and approval of any significant transactions, as well as our management and business affairs, which may prevent new investors from influencing some or all of the foregoing. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, any future debt agreements may preclude us from paying dividends. For the foreseeable future, any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares. Investors seeking cash dividends should not purchase our common stock. See "Dividend Policy" under Item 5 of Part II of this Annual Report for additional information.

Sales, or the possibility of sales, of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity or equity-linked securities.

In addition, as of December 31, 2025, we had 4,328,880 shares of common stock that are subject to outstanding options under our employee benefit plans. All of the shares of common stock issuable upon the exercise of stock options and the shares reserved for future issuance under our employee benefit plans have been registered on a registration statement on Form S-8 under the Securities Act. Accordingly, these shares can be freely sold in the public market upon issuance, subject to volume limitations under Rule 144 for our executive officers and directors and applicable vesting requirements. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

We are an emerging growth company and a smaller reporting company, and the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the closing of our initial public offering completed in January 2024. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer", as defined under the Exchange Act, our annual gross revenues exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in connection with registered securities offerings;

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, unless the SEC determines the new rules are necessary for protecting the public;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this Annual Report. In particular, in this Annual Report, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this exemption and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a merger, acquisition, or other change in control of our company or changes in our board of directors that our stockholders might consider favorable, including transactions in which you might otherwise receive a premium for your shares. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at an annual or special meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than 75% of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than 75% of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue convertible preferred stock on terms determined by the board of directors without stockholder approval and which convertible preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our

amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change in control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated certificate of incorporation designates certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action or proceeding asserting a claim of breach of fiduciary duty owed by any of our current or former directors, officers, employees or agents to us or our stockholders, (iii) any action or proceeding asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws (in each case, as they may be amended from time to time), (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or bylaws, (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware, or (vi) any action asserting a claim against us or any of our directors, officers or employees that is governed by the internal affairs doctrine; provided, however, that this exclusive forum provision does not apply to any action arising under the Exchange Act. Our amended and restated certificate of incorporation further provides that, unless we consent in writing to an alternative forum, the United States District Court for the Eastern District of Pennsylvania will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. We have chosen the United States District Court for the Eastern District of Pennsylvania as the exclusive forum for such Securities Act causes of action because our principal executive offices are located in Newtown Square, Pennsylvania. In addition, our amended and restated certificate of incorporation provides that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. We recognize that the forum selection clause in our amended and restated certificate of incorporation may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the State of Pennsylvania, as applicable. Additionally, the forum selection clause in our amended and restated certificate of incorporation may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. The Court of Chancery of the State of Delaware or the United States District Court for the Eastern District of Pennsylvania may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. Alternatively, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Because the applicability of the exclusive forum provision is limited to the extent permitted by applicable law, we do not intend that the exclusive forum provision would apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. We also acknowledge that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder and that there is uncertainty as to whether a court would enforce an exclusive forum provision for actions arising under the Securities Act.

General Risk Factors

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

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

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act concerning areas such as "say on pay" and proxy access. Emerging growth companies are permitted to implement many of these requirements over a longer period, which may be up to five years from the pricing of our initial public offering in January 2024. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. The increased costs could decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If we fail to maintain effective internal control over financial reporting, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report on the effectiveness of our internal control over financial reporting. When we lose our status as an "emerging growth company" and do not otherwise qualify as a "smaller reporting company" with less than $100.0 million in annual revenue, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with

the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. The identification of material weaknesses could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. The PCAOB has defined a material weakness as "a deficiency, or a combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim statements will not be prevented or detected on a timely basis."

Although we determined that our internal controls over financing reporting were effective as of December 31, 2025, we may in the future identify internal control deficiencies that could rise to the level of a material weakness or uncover other errors in financial reporting. During the course of our evaluation of these material weaknesses, we may identify areas requiring improvement and may be required to design additional enhanced processes and controls to address issues identified through this review. There can be no assurance that such remediation efforts will be successful, that our internal control over financial reporting will be effective as a result of these efforts or that any such future deficiencies identified may not be material weaknesses that would be required to be reported in future periods. In addition, we cannot assure you that our independent registered public accounting firm will be able to attest that such internal controls are effective when they are required to do so.

If we fail to maintain effective disclosure controls and procedures or internal control over financial reporting or remediate any future material weaknesses, you may not be able to rely on the integrity of our financial results, which could result in inaccurate or late reporting of our financial results, as well as delays or the inability to meet our reporting obligations or to comply with the rules and regulations of the Securities and Exchange Commission. Any of these events could result in delisting actions by the Nasdaq Stock Market, investigation and sanctions by regulatory authorities, and stockholder investigations and lawsuits, in addition to adversely affecting our business and the trading price of our common stock.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. If we fail to comply with these laws, we could face civil or criminal liability and other serious consequences for violations, which could harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls and anti-corruption and anti-money laundering laws and regulations, including the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad if and when we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities, and any training or compliance programs or other initiatives we undertake to prevent such activities may not be effective. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. In February 2025, President Trump issued an executive order directing the DOJ to pause enforcement of the FCPA and to issue new enforcement guidelines that take into consideration U.S. national security and the competitiveness of U.S. companies abroad. On June 10, 2025, the DOJ issued a memorandum with guidelines

for enforcing the FCPA. It is unclear how this presidential directive and the DOJ guidelines may affect the biopharmaceutical industry as a whole or our business in particular.

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed as a result of military conflicts in other countries may impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain.

Our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time-consuming or costly.

Our third-party manufacturers or suppliers use, and potential future collaborators will use, biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. The operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, our third-party manufacturers and suppliers cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury at our manufacturers' or suppliers' sites, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our third-party manufacturers' and suppliers' storage or disposal of biologic, hazardous or radioactive materials.

In addition, our third-party manufacturers and suppliers may need to incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time, which may increase the cost of their services to us. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities for our third-party manufacturers and suppliers, which could in turn materially adversely affect our business, financial condition, results of operations and prospects. To the extent we develop our own manufacturing operations in the future, we may similarly incur substantial costs to ensure compliance with these laws, and all the foregoing risks will further apply to us, as well.

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

Our operations and the operations of our suppliers, CROs, CMOs and clinical sites could be subject to earthquakes, power shortages, telecommunications or infrastructure failures, cybersecurity incidents, physical security breaches, water shortages, floods, hurricanes, typhoons, blizzards and other extreme weather conditions, fires, public health pandemics or epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on, or expect to rely on, third-party manufacturers or suppliers to produce our current product candidates and its components and on CROs and clinical sites to conduct our clinical trials, and do not have a redundant source of supply for all components of our product candidate. Our ability to obtain clinical or, if approved, commercial, supplies of our current product candidates or any future product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption, and our ability to commence, conduct or complete our clinical trials in a timely manner could be similarly adversely affected by any of the foregoing. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Unfavorable macroeconomic conditions, political instability and geopolitical events could adversely affect our business, financial condition, stock price, and results of operations.

Our business could be adversely affected by unstable economic and political conditions within the U.S. and foreign jurisdictions, including as a result of an economic downturn and geopolitical events, such as the potential for significant changes in the U.S. federal policies or regulatory environment that affect the geopolitical landscape, changes in or the disruptions of U.S. governmental agencies, whether from a prolonged U.S. federal government shutdown or reduced resources, disruptions in capital markets, changes in international trade relationships and military conflicts. The global credit and financial markets have also generally experienced extreme volatility and disruptions (including as a result of actual or perceived changes in interest rates, inflation, international tariffs and macroeconomic uncertainties), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, global supply chain disruptions, and increases in unemployment rates. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for our product candidates and in our ability to raise additional capital when needed on acceptable terms, if at all.

The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflicts, such as the ongoing conflicts between Russia and Ukraine, Israel and Iran, and Israel and Hamas, terrorism, or other geopolitical events. Sanctions imposed by the U.S. and other countries in response to such conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. Additionally, changes to policy implemented by the U.S. Congress, the current U.S. administration or any new U.S. administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. For example, in 2018 and 2019, increased tariffs were implemented on goods imported into the U.S., particularly from China, Canada, and Mexico. Additionally, in early 2025, the U.S. imposed significant tariffs on imports from other countries, including a baseline tariff of 10% on imports into the U.S. and higher tariffs on multiple designated countries (including the EU Member States, China, Canada, and Mexico), such as "reciprocal" tariffs at varying rates. Such tariffs have prompted retaliatory measures from several countries, which may further escalate.

On April 9, 2025, the U.S. announced that the imposition of most "reciprocal" tariffs would be paused for 90 days pending negotiations with the relevant countries. On September 25, 2025, the current U.S. administration announced a 100% tariff on brand-name or patented drugs unless pharmaceutical companies expand their manufacturing operations in the U.S., and may impose more restrictions on goods. While pharmaceutical products are currently excluded from the baseline and "reciprocal" tariffs imposed by the U.S., such tariffs still apply to the raw materials and other products necessary for the manufacture and formulation of our product candidates. In addition, the current U.S. administration has expressed an intent to impose tariffs on pharmaceutical imports, with the stated policy objective of reshoring pharmaceutical manufacturing to the U.S.

Furthermore, any disruptions to our supply chain as a result of unfavorable global economic conditions, including due to geopolitical conflicts, could negatively impact the timely execution of our ongoing and future clinical trials. In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

Changes in tax law may materially adversely affect our financial condition, results of operations and cash flows, or adversely impact the value of an investment in our common stock.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations

and financial performance. We urge our investors to consult with their legal and tax advisors with respect to any changes in tax law and the potential tax consequences of investing in our common stock.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If one or more of the analysts who covers us downgrades our stock, or if we fail to meet the expectations of one or more of these analysts, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, even if ultimately decided in our favor, it could result in substantial costs that may not be fully covered by insurance, and a diversion of our management's attention and resources, which could harm our business.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity

We recognize the critical importance of maintaining the trust and confidence of patients, business partners and employees toward our business and are committed to protecting the confidentiality, integrity and availability of our business operations and systems. Our board of directors, led by the audit committee, is actively involved in oversight of our Enterprise Risk Management or ERM activities, and cybersecurity represents an important element of our overall approach to risk management. Our cybersecurity policies, standards, processes and practices are based on recognized frameworks established by the National Institute of Standards and Technology, or NIST, and other applicable industry standards.

Cybersecurity Risk Management and Strategy; Effect of Risk

We face risks related to cybersecurity such as unauthorized access, cybersecurity attacks and other security incidents, including as perpetrated by hackers and unintentional damage or disruption to hardware and software systems, loss of data, and misappropriation of confidential information. To identify and assess material risks from cybersecurity threats, we maintain a comprehensive cybersecurity program to ensure our systems are effective and prepared for information security risks, including regular oversight of our programs for security monitoring for internal and external threats to ensure the confidentiality and integrity of our information assets. We consider risks from cybersecurity threats alongside other company risks as part of our ERM process. We employ a range of tools and services, including regular network and endpoint monitoring, audits, vulnerability assessments, penetration testing and threat modeling to inform our risk identification and assessment. As discussed in more detail under "Cybersecurity Governance" below, our audit committee provides oversight of our cybersecurity risk management and strategy processes, which are led by our Chief Operating Officer.

We also identify our cybersecurity threat risks by comparing our processes to standards set by NIST as well as by engaging experts to attempt to infiltrate our information systems. To provide for the availability of critical data and systems, maintain regulatory compliance, manage our material risks from cybersecurity threats, and protect against and respond to cybersecurity incidents, we undertake the following activities:

- monitor emerging data protection laws and implement changes to our processes that are designed to comply with such laws;

- through our policies, practices and contracts (as applicable), require employees, as well as third parties that provide services on our behalf, to treat confidential information and data with care;

- employ technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence;

- provide regular training for our employees and contractors regarding cybersecurity threats as a means to equip them with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices;

- conduct regular phishing email simulations for all employees and contractors with access to our email systems to enhance awareness and responsiveness to possible threats;

- leverage the NIST incident handling framework to help us identify, protect, detect, respond and recover when there is an actual or potential cybersecurity incident; and

- carry information security risk insurance that provides protection against the potential losses arising from a cybersecurity incident.

Our business continuity policy coordinates the activities we take to prepare for, detect, respond to and recover from cybersecurity incidents, which include processes to triage, assess severity for, escalate, contain, investigate and remediate the incident, as well as to comply with potentially applicable legal obligations and mitigate damage to our business and reputation.

As part of the above processes, we regularly engage with consultants, auditors and other third parties, including annually having a third-party review our cybersecurity program to help identify areas for continued focus, improvement and compliance.

Our processes also address cybersecurity threat risks associated with our use of third-party service providers, including our suppliers and manufacturers or who have access to patient and employee data or our systems. In addition, cybersecurity considerations affect the selection and oversight of our third-party service providers. Additionally, we generally require those third parties that could introduce significant cybersecurity risk to us to agree by contract to manage their cybersecurity risks in specified ways, and to agree to be subject to cybersecurity audits, which we conduct as appropriate.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, in Item 1A, “Risk Factors”, which disclosures are incorporated by reference herein.

In the last three fiscal years, we have not experienced any material cybersecurity incidents and the expenses we have incurred from cybersecurity incidents were immaterial. This includes penalties and settlements, of which there were none.

Cybersecurity Governance; Management

Cybersecurity is an important part of our risk management processes and an area of focus for our board of directors and management. In general, our board of directors oversees risk management activities designed and implemented by our management, and considers specific risks, including, for example, risks associated with our strategic plan, business

operations, and capital structure. The audit committee of our board of directors is responsible for the oversight of risks from cybersecurity threats.

Periodically, our audit committee, and annually, our board of directors receives an update from management of our cybersecurity threat risk management and strategy processes covering topics such as data security posture, results from third-party assessments, progress towards pre-determined risk-mitigation-related goals, our incident response plan, and material cybersecurity threat risks or incidents and developments, as well as the steps management has taken to respond to such risks. In such sessions, our audit committee generally receives information that includes a cybersecurity summary and other information discussing current and emerging material cybersecurity threat risks, and describing our ability to mitigate those risks, as well as recent developments, evolving standards, technological developments and information security considerations arising with respect to our peers and third parties. Our audit committee and board of directors also receive prompt and timely information regarding any cybersecurity incident that meets establishing reporting thresholds, as well as ongoing updates regarding any such incident until it has been addressed.

Members of our audit committee and board of directors are also encouraged to regularly engage in conversations with management on cybersecurity-related news events and discuss any updates to our cybersecurity risk management and strategy programs. Material cybersecurity threat risks are also considered during separate board meeting discussions of important matters like ERM, operational budgeting, business continuity planning, mergers and acquisitions, brand management, and other relevant matters.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by our Chief Operating Officer in consultation with our Chief Financial Officer and General Counsel. Such individuals and their respective teams have collectively over a dozen years of prior work experience in various roles involving managing information security, developing cybersecurity strategy, implementing effective information and cybersecurity programs. These management team members are informed about and monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan. As discussed above, these management team members report to the audit committee of our board of directors quarterly, and our board of directors annually about cybersecurity threat risks, among other cybersecurity related matters.

Item 2. Properties

We currently lease office space in and around the San Francisco Peninsula and Washington, D.C./Maryland area.

We lease office space at 1350 Bayshore Highway, Burlingame, CA 94041, containing approximately 7,906 square feet of office space pursuant to a lease agreement that expires in August 2027. This lease replaced a lease at the same address which expired in January 2026.

We also lease office space at 9841 Washingtonian Boulevard, Gaithersburg, MD 20878, pursuant to a lease agreement that expires in February 2027. This lease replaced a lease at the same address which expired in February 2026. The initial lease term for this lease was less than twelve months.

We believe these facilities will be adequate for the foreseeable future and that suitable additional or substitute space will be available as and when needed.

Item 3. Legal Proceedings

From time to time, we may be subject to legal proceedings. We are not currently a party to or aware of any proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 4. Mine Safety Disclosures

None.

PART II

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

Our common stock has been listed on the Nasdaq Global Market under the symbol "AVBP" since January 26, 2024. Prior to that date there was no public trading market for our common stock.

Holders

As of February 27, 2026, there were approximately 5 holders of record of our common stock. We believe actual number of stockholders is greater than this number of record holders. The approximate number of holders includes holders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose share may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors might deem relevant.

Recent Sales of Unregistered Securities

(a) Issuances of Securities

In multiple closings held between December 2022 and March 2023, we issued and sold an aggregate of 147,619,034 shares of Series B convertible preferred stock at a purchase price of $1.05 per share for aggregate gross cash consideration of $155.0 million.

No underwriters were involved in the foregoing issuances of securities. These securities described in this section (a) were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All holders of securities described above represented to us in connection with their purchase or issuance that they were accredited investors and were acquiring the securities for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The holders received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

(b) Grants of Stock Options

During 2024, we granted to certain of our directors, employees and consultants (in connection with services provided to us by such persons) options to purchase 1,137,307 shares of our common stock with a weighted average exercise price of $11.10 under our 2021 Employee, Director and Consultant Equity Incentive Plan, as amended (2021 Plan).

The stock options and the common stock issuable upon the exercise of such options as described in this section (b) were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the

Securities Act or the exemption set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information. On February 2, 2024 and March 3, 2025, we filed registration statements on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to our equity compensation plans.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of capital stock described in this Item 5 include appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

Use of Proceeds

On January 25, 2024, our registration statement on Form S-1 (File No 333-276397) relating to our initial public offering of common stock was declared effective by the SEC. Upon the closing of the initial public offering, we issued 11,180,555 shares of common stock (including the exercise in full by the underwriters of their option to purchase an additional 1,458,333 shares of common stock) at a public offering price of $18.00 per share. We received net proceeds from the initial public offering of $183.2 million, after deducting the underwriting discounts and commissions. None of the expenses associated with our initial public offering were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates.

There has been no material change in the planned use of proceeds from the initial public offering from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on January 26, 2024.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

None.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the "Risk Factors" section of this Annual Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company dedicated to the identification, development and commercialization of differentiated medicines to address the unmet medical needs of patients with cancers. We seek to utilize our team's deep drug development experience to maximize the potential of our lead product candidate, firmonertinib, and advance a pipeline of novel therapeutics, such as next-generation antibody drug conjugates, including ARR-217 (MRG007) through approval and commercialization in patients suffering from cancer, with an initial focus on solid tumors. Firmonertinib is currently being evaluated in multiple clinical trials across a range of EGFRm in NSCLC. We are conducting a pivotal Phase 3 clinical trial of firmonertinib in treatment naive, or first-line, patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations and a pivotal Phase 3 clinical trial of

firmonertinib in first-line patients with locally advanced or metastatic EGFRm NSCLC with PACC mutations. We are also conducting a Phase 1 clinical trial of ARR-217 in patients with unresectable locally advanced or metastatic solid tumors.

We received Breakthrough Therapy Designation for firmonertinib for first line EGFRm NSCLC with exon 20 insertion from the FDA in October 2023, and Orphan Drug Designation for treatment of NSCLC with EGFRm or HER2 mutations or HER4 mutations in February 2024. A product candidate can receive BTD if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development although BTD may not result in a faster development process, review or approval and does not increase the likelihood that the product candidate will ultimately receive FDA approval for any indication.

In 2021, we licensed from Allist the right to develop and commercialize firmonertinib worldwide, with the exception of greater China, which includes mainland China, Hong Kong, Macau and Taiwan. Firmonertinib is an investigational, novel, EGFR mutant-selective TKI that we are developing for the treatment of NSCLC patients across a broader set of EGFRm than are currently served by approved EGFR TKIs. Firmonertinib is currently only approved and commercially distributed by Allist in China as a first-line therapy to treat classical EGFRm NSCLC. The FDA has not approved firmonertinib for any use. We selected firmonertinib for global development against nonclassical, or uncommon, mutations based on preliminary reductions in tumor size observed in seven out of ten patients with EGFR exon 20 insertion mutations treated with firmonertinib in the ongoing Phase 1b clinical trial, the FAVOUR trial, conducted by Allist in China, and preclinical activity in PACC mutations, each a subtype of uncommon mutation. In a subsequent interim data readout from the FAVOUR trial of firmonertinib in first-line patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations who were administered a 240 mg once-daily dose of firmonertinib, 79% of patients (n=22 out of 28 patients) were observed to experience a reduction in tumor size of at least 30%. In a final analysis from the Phase 1B FURTHER trial of firmonertinib, which included a cohort of EGFRm NSCLC with PACC mutations, we observed 16.0 months mPFS with firmonertinib 240 mg in first-line, cORR 68.2% (n=15 out of 22 1L patients at 240 mg) and DOR 14.6 months, and confirmed CNS responses with firmonertinib including CRs.

As one of the most prevalent cancers in the world, lung cancer imposes a significant global burden on human health, and EGFRm NSCLC represents a significant proportion of those affected. Despite progress in the therapeutic landscape for EGFRm NSCLC, many patients, particularly those with uncommon mutations, such as exon 20 insertions or PACC mutations, are underserved by existing treatments. In an interim data readout from the FAVOUR trial of firmonertinib in first-line patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations, 79% of patients (n=22 out of 28 patients) who were administered a 240 mg once-daily dose of firmonertinib were observed to experience a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression as measured by RECIST 1.1 criteria. This measurement of reduction is the threshold in this trial for a partial response and for inclusion in determination of the ORR, which is the primary endpoint of this trial. In the same interim data readout, those 79% of patients were observed to experience a 15.2 month median DOR. Interim results may not be indicative of final results; however, we believe these interim clinical results underscore firmonertinib's potential in patients whose tumors contain an uncommon EGFRm.

We have entered into the Allist License Agreement, pursuant to which, we have, among other things, secured an exclusive, royalty bearing and sublicensable license under certain intellectual property, including patents and know-how, owned or controlled by Allist to develop and commercialize any product containing firmonertinib or any of its salts or derivatives as an active ingredient of a product, which is led by a joint collaboration committee, comprising of representatives from both Allist and us. Under the Allist License Agreement, we are obligated to pay Allist milestone payments up to an aggregate of $765.0 million upon the achievement of certain development, regulatory and sales milestone events as set forth in the Allist License Agreement. During the year ended December 31, 2025, we incurred $5.0 million in clinical milestones to Allist. We are also obligated under the Allist License Agreement to pay Allist tiered royalties based on net sales of Licensed Products (as defined in the Allist License Agreement). See "Business — Licenses, Partnerships and Collaborations — Allist Agreements."

We have entered into the Lepu Biopharma Agreement, pursuant to which, we have, among other things, secured an exclusive, royalty bearing and sublicensable license under certain intellectual property, including patents and know-how, owned or controlled by Lepu Biopharma to develop and commercialize any product containing ARR-217 or the antibody component of ARR-217. Further, we are obligated to pay Lepu Biopharma milestone payments up to an aggregate of approximately $1.17 billion upon the achievement of certain development, regulatory and sales milestone events as set forth in the Lepu Biopharma Agreement, as defined herein. We are also obligated under the Lepu Biopharma Agreement to pay Lepu Biopharma tiered royalties based on net sales of Licensed Products, as defined herein. See "Business — Licenses, Partnerships and Collaborations — Lepu Biopharma Agreement".

Since our inception in April 2021, we have devoted substantially all of our resources to organizing and staffing our company, acquiring the rights to develop firmonertinib, ARR-217, and clinical development of firmonertinib, business planning, raising capital, identifying potential product candidates, enhancing our intellectual property portfolio and undertaking research and clinical and preclinical studies for our development programs. We do not have any products approved for sale and have not generated any revenue from product sales or otherwise. We have funded our operations to date primarily through the private placement of convertible preferred stock and through our initial public offering of common stock in January 2024, our "at-the-market" offering, and our underwritten public offering of common stock and pre-funded warrants to purchase common stock in July 2025.

We have incurred significant operating losses since our inception and have not yet generated any revenue. Our net losses were $166.3 million and $80.5 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $404.6 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our preclinical studies, clinical trials and our expenditures on other research and development activities. We expect to continue to incur losses for the foreseeable future. We anticipate these losses will increase substantially as we:

- advance our product candidates through clinical trials;
- acquire or in-license additional product candidates;
- advance our preclinical programs to clinical trials;
- further invest in our pipeline;
- further support our external partners' manufacturing capabilities;
- seek regulatory approval for our product candidates;
- pursue commercialization of our product candidates;
- maintain, expand, protect and defend our intellectual property portfolio;
- secure facilities to support continued growth in our research, development and commercialization efforts;
- increase our headcount to support our development efforts and to expand our clinical development team; and
- incur additional costs and headcount associated with operating as a public company.

In addition, if we obtain regulatory approval for firmonertinib or any product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more product candidates. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through public or private equity offerings, debt financings, collaborations and licensing arrangements or other capital sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or

future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Key Components of Our Results of Operations

Operating Expenses

Research and Development Expenses

To date, our research and development expenses have been related primarily to the development of firmonertinib, preclinical studies and other clinical activities related to our portfolio. Research and development costs are expensed as incurred and payments made prior to the receipt of goods or services to be used in research and development are deferred and recognized when the goods or services are received.

Research and development costs include:

- salaries, payroll taxes, employee benefits and stock-based compensation expenses for those individuals involved in research and development efforts;
- external research and development costs incurred under agreements with CROs and consultants to conduct our clinical trials and other preclinical studies;
- costs related to manufacturing our product candidates, including fees paid to third-party manufacturers and raw material suppliers;
- license fees and research funding; and
- other allocated expenses, which include direct and allocated expenses, insurance, equipment and other supplies.

Our direct research and development expenses consist principally of external costs, such as fees paid to CROs and consultants in connection with our clinical trials for firmonertinib, preclinical and toxicology studies and costs related to manufacturing materials for clinical and preclinical studies. A significant majority of our direct research and development costs have been related to firmonertinib. We deploy our personnel resources across all of our research and development activities.

We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of firmonertinib and the identification and development of new product candidates. We cannot determine with certainty the timing of initiation, the duration or the completion costs of future clinical trials and preclinical studies of product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates and development programs to pursue and how much funding to direct to each product candidate or program on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our future clinical development costs may vary significantly based on factors such as:

- per patient trial costs;
- the number of patients needed to determine a recommended dose;
- the number of trials required for approval;
- the number of sites included in the trials;

- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, payroll taxes, employee benefits and stock-based compensation expenses for those individuals in executive, finance and other administrative functions. Other significant costs include legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services, and insurance costs. We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities and, if any product candidates receive marketing approval, commercialization activities. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with operating as a public company.

Interest and Investment Income

Interest and investment income consists of interest earned on our cash, cash equivalents and short-term investments and the accretion of premiums and amortization of discounts on marketable securities.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

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

	Year Ended December 31,		
(in thousands)	2025	2024	Change
Operating expenses:			
Research and development	$ 153,351	$ 79,004	$ 74,347
General and administrative	24,183	15,304	8,879
Total operating expenses	177,534	94,308	83,226
Operating loss	(177,534)	(94,308)	(83,226)
Interest and investment income	11,226	13,820	(2,594)
Net loss	$ (166,308)	$ (80,488)	$ (85,820)

Research and Development

We track outsourced clinical and preclinical costs and other external research and development costs associated with our lead product candidate, firmonertinib, and other early-stage programs. We do not track internal research and

development costs by product candidate. The following table summarizes our research and development expenses for the years ended December 31, 2025 and 2024:

(in thousands)	Year Ended December 31, 2025	2024	Change
Firmonertinib:			
FURTHER	$ 9,838	$ 12,272	$ (2,434)
FURVENT	48,741	34,135	14,606
FAVOUR	397	272	125
Other Firmonertinib costs	8,634	4,187	4,447
Total Firmonertinib	67,610	50,865	16,745
Early-stage programs	55,470	10,940	44,530
Personnel-related and other internal costs	30,271	17,199	13,072
Total research and development expenses	$ 153,351	$ 79,004	$ 74,347

Research and development expenses were $153.4 million and $79.0 million for the years ended December 31, 2025 and 2024, respectively. The increase of $74.3 million was primarily due to an increase of $44.5 million in preclinical discovery work, and a $13.1 million increase due to higher personnel-related costs due to increased headcount. Cost increases related to early-stage programs were largely due to a $40.0 million one-time up front payment pursuant to our collaboration with Lepu. Costs related to firmonertinib increased $16.7 million as a result of increased costs related to our FURVENT Phase 3 clinical trial of $14.6 million, $4.4 million for general firmonertinib costs, and $0.1 million for our FAVOUR trial, offset by a decrease of $2.4 million in costs related to our FURTHER Phase 1 clinical trial.

General and Administrative

General and administrative expenses were $24.2 million and $15.3 million for the years ended December 31, 2025 and 2024, respectively. The increase of $8.9 million was due primarily to increases of $7.3 million in personnel-related expenses, $1.8 million in professional services and infrastructure costs, offset by $0.2 million in general corporate expenses.

Interest and Investment Income

Interest and investment income was $11.2 million and $13.8 million for the years ended December 31, 2025 and 2024, respectively. The decrease is due to lower rates of return on lower invested balances year-over-year.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through the private placement of convertible preferred stock our initial public offering of common stock, our "at-the-market" offering, and our underwritten public offering of common stock and pre-funded warrants to purchase common stock in July 2025. We have raised gross proceeds of $305.0 million from the issuance of convertible preferred stock since our inception through December 31, 2025. Additionally, in the first quarter of 2024, we completed our initial public offering of 11,180,555 shares of our common stock at a price to the public of $18.00 per share, including the exercise in full by the underwriters of their option to purchase 1,458,333 additional shares of our common stock. Including the option exercise, our aggregate net proceeds from the offering were $183.2 million, net of underwriting discounts, commissions and offering costs. As of December 31, 2025, we had cash and cash equivalents, and short and long-term investments of $312.8 million in the aggregate.

On February 3, 2025, we filed an automatic shelf registration statement on Form S-3ASR (File No. 333-284661) with the SEC. The shelf registration statement consists of (i) a base prospectus pursuant to which we may offer and sell, from time to time, shares of our common stock, shares of our preferred stock, various series of debt securities, warrants, rights, and/or units to purchase any of such securities in one or more registered offerings, and (ii) a prospectus supplement pursuant to which we may offer and sell, from time to time, up to $250 million of shares of common stock in "at-the-market" offerings. During the year ended December 31, 2025, we sold 5,560,266 shares of common stock

pursuant to our Open Market Sale Agreement[SM] with Jefferies LLC (ATM Program) for total proceeds of $122.2 million, net of commissions and other expenses. As of December 31, 2025, we have approximately $123.3 million remaining for future issuances of common stock pursuant to the ATM Program. There has been no material change in the planned use of proceeds as described in the shelf registration statement. None of the offering expenses were paid or payable, directly, or indirectly, to our directors, officers, or persons owning 10% or more of any class of equity securities or to our affiliates.

In May 2025, we entered into a $75 million loan and security agreement with Silicon Valley Bank (Loan Agreement), a division of First Citizens Bank & Trust Company. The credit facility provides the right, but not the obligation, to draw up to $75 million of capital, of which $40 million will be available if certain conditions and milestones are met. In March 2026, we entered into an amendment of the Loan Agreement in which such conditions and milestones were amended. No amounts have been drawn on this facility as of the date of this report.

On July 3, 2025, we closed an underwritten public offering (the July 2025 Offering) in which we issued and sold an aggregate of 3,059,615 shares of our common stock, including the exercise in full of the underwriters' option to purchase 576,923 additional shares of common stock, at a public offering price of $19.50 per share, and, in lieu of shares of common stock to certain investors, pre-funded warrants to purchase up to 1,363,469 shares of common stock at a public offering price of $19.4999 per pre-funded warrant, which represents the per share public offering price for the shares less the $0.0001 per share exercise price for each pre-funded warrant. The proceeds to us, net of underwriting discounts, commissions, and other expenses, were $80.5 million.

Future Funding Requirements

We plan to continue to fund our operating expenses and capital expenditure requirements through additional public or private equity offerings, debt financings, collaborations and licensing arrangements or other capital sources. Debt or equity financing or collaborations and partnerships with other entities may not be available on a timely basis, on acceptable terms, or at all. In addition, we may be required to scale back or discontinue the advancement of product candidates, reduce headcount or reduce other operating expenses. This could have an adverse impact on our ability to achieve certain of our planned objectives, and thus, materially harm our business. Our ability to successfully transition to profitability will depend upon obtaining additional financing and achieving a level of product sales adequate to support our cost structure. We cannot be assured that we will ever be profitable or generate positive cash flows from operating activities.

We believe that our existing cash and cash equivalents and short and long-term investments will be sufficient to meet our anticipated cash requirements through at least twelve months from the issuance date of these financial statements. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect.

Our future capital requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of drug discovery, preclinical studies and clinical trials of our lead product candidate, firmonertinib, and any other product candidates;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- the cost of manufacturing firmonertinib, if approved, and future product candidates for clinical trials in preparation for marketing approval and in preparation for commercialization;
- the costs of any third-party products used in our combination clinical trials that are not covered by such third party or other sources;

- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the receipt of marketing approval and revenue received from any potential commercial sales of firmonertinib or other product candidates;
- the cost of commercialization activities for firmonertinib and future product candidates we develop if we receive marketing approval, including marketing, sales and distribution costs;
- the emergence of competing therapies and other adverse market developments;
- the ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the extent to which we in-license or acquire other products and technologies; and
- the costs of operating as a public company.

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

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,	
(in thousands)	2025	2024
Net cash (used in) provided by:		
Operating activities	$ (160,588)	$ (70,212)
Investing activities	(71,228)	(192,465)
Financing activities	203,063	186,581
Net decrease in cash and cash equivalents	$ (28,753)	$ (76,096)

Operating Activities

Net cash used in operating activities was $160.6 million for the year ended December 31, 2025 reflecting our net loss of $166.3 million, $3.0 million of amortization and accretion of discounts and premiums, and a $3.8 million net change in our operating assets and liabilities attributable to the timing in which we pay our vendors for research and development activities. These were offset by $12.5 million in stock-based compensation.

Net cash used in operating activities was $70.2 million for the year ended December 31, 2024 reflecting our net loss of $80.5 million that was offset by $3.2 million in stock-based compensation and a $7.1 million net change in our

operating assets and liabilities attributable to the timing in which we pay our vendors for research and development activities.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2025 included $272.9 million of purchases of short and long-term investments, offset by $201.7 million of maturities of short-term investments.

Net cash used in investing activities for the year ended December 31, 2024 included $194.2 million of purchases of short and long-term investments, offset by $1.7 million of maturities of investments.

Financing Activities

Net cash provided by financing activities was $203.1 million for the year ended December 31, 2025, due to $80.5 million of net proceeds from our July 2025 offering and $122.2 million in net proceeds from the issuance of shares under the "at-the-market" program. There were also $0.5 million of proceeds from the exercise of stock options.

Net cash provided by financing activities was $186.6 million for the year ended December 31, 2024, due to $186.0 million of net proceeds from our initial public offering in January 2024, in addition to $0.6 million in proceeds from the exercise of stock options.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2025 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less Than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
			(in thousands)		
Operating lease obligations	$ 14	$ 14	$ —	$ —	$ —
Total	$ 14	$ 14	$ —	$ —	$ —

As of December 31, 2025, except for the operating lease, we did not have any long-term obligations, capital lease obligations, purchase obligation or long-term liabilities. We enter into contracts in the normal course of business with third-party CROs and clinical trial sites for our clinical trials, and with supply vendors for other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts. Amounts related to contingent milestone payments under our license and collaboration agreements are not yet considered contractual obligations, and not included in the table above, as they are contingent on the successful achievement of certain clinical, regulatory and commercial milestones.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued research and development and stock-based compensation expenses. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 to our accompanying financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies to be most critical to the preparation of our financial statements.

Research and Development Accruals

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

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

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

Milestone payments within our licensing and collaboration arrangements will be recognized when achievement of the milestone is deemed probable to occur. To the extent products are commercialized and future economic benefit has been established, commercial milestones that become probable are capitalized and amortized over the estimated remaining useful life of the intellectual property. In addition, we will accrue royalty expense and sublicense non-royalty payments, as applicable, for the amount we are obligated to pay, with adjustments as sales are made.

Stock-Based Compensation Expense

We maintain a stock-based compensation plan as a long-term incentive for employees and non-employee consultants. The plan allows for the issuance of incentive stock options and non-qualified stock options.

We recognize stock-based compensation expense for stock options on a straight-line basis over the requisite service period, which is the vesting period of the awards. Our stock-based compensation expense is based upon the grant date fair value of stock options estimated using the Black-Scholes option pricing model.

Estimating the fair value of stock options as of the grant date using the Black-Scholes option pricing model is affected by input assumptions which consider a number of variables. The input assumption relating to the fair value of our common stock for grants made prior to our initial public offering was subjective and required judgment to develop.

JOBS Act and Emerging Growth Company Status

As an emerging growth company under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of our initial public offering, (ii) the last day of the fiscal year in which we have

total annual gross revenue of at least $1.235 billion, (iii) the day on which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Recent Accounting Pronouncements

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 3 to our accompanying financial statements appearing elsewhere in this Annual Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our cash and cash equivalents consist of cash held in an interest-bearing savings account and money market account. As a result, we believe that our exposure to interest rate risk is not significant, and a hypothetical 1.0% change in market interest rates during any of the periods presented would not have had a material impact on the total value of our portfolio.

Foreign Currency

We do not regularly incur any material expenses with vendors outside the United States or that are denominated in currencies other than the U.S. dollar. We may incur such expenses in the future at which point exchange rate fluctuations might adversely affect our expenses, results of operations, financial position and cash flows. To date, exchange rate fluctuations have not had a material effect on our results of operations.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe inflation has had a material effect on our results of operations during the periods presented and do not anticipate a material impact going forward.

Item 8. Financial Statements and Supplementary Data

ARRIVENT BIOPHARMA, INC.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of ArriVent BioPharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of ArriVent BioPharma, Inc. (the "Company") as of December 31, 2025, and the related statement of operations and comprehensive loss, of convertible preferred stock and stockholders' equity (deficit) and of cash flows for the year then ended, including the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ PricewaterhouseCoopers LLP
Philadelphia, Pennsylvania
March 5, 2026

We have served as the Company's auditor since 2025.

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
ArriVent BioPharma, Inc.:

Opinion on the Financial Statements
We have audited the accompanying balance sheet of ArriVent BioPharma, Inc. (the Company) as of December 31, 2024, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for the year then ended, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

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

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

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

/s/ KPMG LLP

We served as the Company's auditor from 2023 to 2025.

Boston, Massachusetts
March 3, 2025

ARRIVENT BIOPHARMA, INC.

BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 45,540	$ 74,293
Short-term investments	267,281	144,570
Prepaid expenses and other current assets	20,076	8,116
Total current assets	332,897	226,979
Long-term investments	—	47,683
Right of use assets – operating leases	13	154
Deferred offering costs	69	—
Other assets	190	126
Total assets	$ 333,169	$ 274,942
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,934	$ 3,782
Accrued expenses	19,997	13,330
Operating lease liabilities	14	162
Total current liabilities	25,945	17,274
Operating lease liabilities, net of current amount	—	14
Total liabilities	25,945	17,288
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock $0.0001 par value, 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock $0.0001 par value, 200,000,000 shares authorized; 42,452,251 and 33,706,765 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	4	3
Additional paid-in capital	711,847	496,195
Accumulated deficit	(404,641)	(238,333)
Accumulated other comprehensive income (loss)	14	(211)
Total stockholders' equity	307,224	257,654
Total liabilities and stockholders' equity	$ 333,169	$ 274,942

See accompanying notes to financial statements.

ARRIVENT BIOPHARMA, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 153,351	$ 79,004
General and administrative	24,183	15,304
Total operating expenses	177,534	94,308
Operating loss	(177,534)	(94,308)
Interest and investment income	11,226	13,820
Net loss	(166,308)	(80,488)
Unrealized gain (loss) on marketable securities	225	(211)
Total other comprehensive gain (loss)	225	(211)
Total comprehensive loss	$ (166,083)	$ (80,699)
Share information:		
Net loss per share attributable to common stockholders, basic and diluted	$ (4.32)	$ (2.56)
Weighted-average shares of common stock outstanding, basic and diluted	38,462,600	31,469,328

See accompanying notes to financial statements.

ARRIVENT BIOPHARMA, INC.

STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share and per share data)

	Series A convertible preferred stock		Series B convertible preferred stock		Common stock		Additional paid-in capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, January 1, 2024	150,000,000	$ 149,865	147,619,034	$ 154,625	2,745,480	$ —	$ 4,652	$ —	$ (157,845)	$ (153,193)
Issuance of common stock in initial public offering, net of issuance costs of $18,032	—	—	—	—	11,180,555	1	183,216	—	—	183,217
Conversion of convertible preferred stock into common stock	(150,000,000)	(149,865)	(147,619,034)	(154,625)	19,567,306	2	304,488	—	—	304,490
Exercise of stock options	—	—	—	—	213,424	—	631	—	—	631
Stock-based compensation expense	—	—	—	—	—	—	3,208	—	—	3,208
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(211)	—	(211)
Net loss	—	—	—	—	—	—	—	—	(80,488)	(80,488)
Balance, December 31, 2024	—	—	—	—	33,706,765	3	496,195	(211)	(238,333)	257,654
Issuance of common stock and pre-funded warrants net of issuance costs of $10,667	—	—	—	—	8,619,881	1	202,630	—	—	202,631
Exercise of stock options	—	—	—	—	125,605	—	502	—	—	502
Stock-based compensation expense	—	—	—	—	—	—	12,520	—	—	12,520
Unrealized gain on marketable securities	—	—	—	—	—	—	—	225	—	225
Net loss	—	—	—	—	—	—	—	—	(166,308)	(166,308)
Balance, December 31, 2025	—	$ —	—	$ —	42,452,251	$ 4	$ 711,847	$ 14	$ (404,641)	$ 307,224

See accompanying notes to financial statements.

ARRIVENT BIOPHARMA, INC.

STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (166,308)	$ (80,488)
Adjustment to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	12,520	3,208
Amortization/Accretion of bond discounts/premiums	(3,026)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(12,561)	1,464
Other assets	—	(20)
Accounts payable	2,141	(751)
Accrued expenses	6,667	6,377
Operating lease liabilities	(21)	(2)
Net cash used in operating activities	(160,588)	(70,212)
Cash flows from investing activities:		
Purchase of short-term and long-term investments	(272,934)	(194,164)
Sales and maturities of short-term and long-term investments	201,706	1,699
Net cash used in investing activities	(71,228)	(192,465)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	202,631	185,950
Proceeds from the exercise of stock options	502	631
Payment of deferred financing costs	(70)	—
Net cash provided by financing activities	203,063	186,581
Net decrease in cash and cash equivalents	(28,753)	(76,096)
Cash and cash equivalents at beginning of the year	74,293	150,389
Cash and cash equivalents at end of the year	$ 45,540	$ 74,293
Supplemental disclosures of non-cash financing and investing activities		
Deferred offering costs transferred to additional paid-in-capital	$ 300	$ 2,732

See accompanying notes to financial statements.

(1) Background

ArriVent BioPharma, Inc., a Delaware corporation (the "Company"), founded on April 14, 2021, is a clinical-stage biopharmaceutical company focused on identifying, licensing and globalizing top biopharma innovations from around the world to deliver important medicines to patients. In June 2021, the Company entered into a license agreement with Shanghai Allist Pharmaceuticals Co. Ltd. ("Allist") which granted the Company an exclusive license under certain intellectual property owned or controlled by Allist to develop, manufacture and commercialize any product containing firmonertinib or any of its derivatives as an active ingredient, for all uses, in all countries and territories other than greater China, which includes mainland China, Hong Kong, Macau and Taiwan (See Note 11). The Company's lead development candidate, firmonertinib, is a third-generation tyrosine kinase inhibitor currently being evaluated in multiple clinical trials across a range of epidermal growth factor receptor mutations in non-small cell lung cancer ("NSCLC"), many for which there are limited treatment options.

On January 30, 2024, the Company completed the closing of its initial public offering of 9,722,222 shares of common stock at a price of $18.00 per share. Additionally, the underwriters exercised their option to purchase an additional 1,458,333 shares of common stock at a price of $18.00 per share. The shares of common stock began trading on The Nasdaq Global Market on January 26, 2024, under the symbol "AVBP". The Company received net proceeds of $183.2 million, after deducting underwriting discounts and commissions and other offering expenses. In addition, as a result of the closing of the Company's initial public offering, the Company's Series A and Series B convertible preferred stock converted into 19,567,306 shares of common stock in January 2024.

(2) Development-Stage Risks and Liquidity

The Company has incurred losses since inception and has an accumulated deficit of $404.6 million as of December 31, 2025. The Company has concluded that the aggregate balance of cash and cash equivalents and marketable securities of $312.8 million as of December 31, 2025 are sufficient to sustain planned operations through at least twelve months from the issuance date of these financial statements.

The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales from its product candidates currently in development; as a result, additional capital will be needed to fund its future operating and capital requirements. There can be no assurance that the Company will be able to raise sufficient additional capital on acceptable terms, if at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, the Company's financial condition or results of operations may be materially adversely affected.

The Company is subject to those risks associated with any specialty biotechnology company that has substantial expenditures for research and development. In addition, geopolitical tensions, volatility of capital markets, and other adverse macroeconomic events, including those due to inflationary pressures, changing interest rates, bank instability and the ability of the U.S. government to manage federal debt limits, as well as the potential impact of other health crises on the global financial markets, may reduce the Company's ability to access capital, which could negatively affect its liquidity.

(3) Summary of Significant Accounting Policies

(a) Basis of Presentation

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). Any references in these notes to applicable guidance are meant to refer to GAAP as found in Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") promulgated by the Financial Accounting Standards Board ("FASB").

(b) Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from such estimates. Estimates and assumptions are periodically reviewed, and the effects of revisions are reflected in the financial statements in the period they are determined to be necessary.

Significant areas that require management's estimates include the fair value of the Company's common stock prior to its initial public offering, and accrued research and development expenses.

(c) Fair Value Measurements

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

- Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.

- Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.

- Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at the measurement date.

Management believes that the carrying amounts of cash equivalents and accounts payable approximate fair value due to the short-term nature of those instruments.

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between Level 1, Level 2 or Level 3 during the years ended December 31, 2025 and 2024.

(d) Cash equivalents

The Company considers all highly liquid investment instruments with a remaining maturity when purchased of three months or less to be cash equivalents. Investments qualifying as cash equivalents consist of money market funds, including money market funds held in a sweep account. Cash equivalents are stated at cost plus accrued interest, which approximates fair value. The amount of cash equivalents included in cash and cash equivalents was approximately $40.5 million and $69.3 million at December 31, 2025 and 2024, respectively.

(e) Investments

The Company classifies all of its investments as available-for-sale based upon its intent with regard to such investments. The Company classifies investments as short-term when their remaining contractual maturities are one year or less from the balance sheet date, and as long-term when the investment has a remaining contractual maturity of more than one year from the balance sheet date. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in other comprehensive income (loss). The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest and investment income. Realized gains and losses and declines in value judged to be other than temporary on available-for-sale securities, are included in interest and investment income.

The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest and investment income. To determine whether an other-than-temporary impairment exists, the Company considers whether it has the ability and intent to hold the investment until a market price recovery, and whether evidence indicating the recoverability of the cost of the investment outweighs evidence to the contrary.

(f) Concentration of credit risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and short and long-term investments. The Company maintains its balances at high quality, accredited financial institutions and, accordingly, it believes such funds are subject to minimal credit risk. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on these balances. The Company has no financial instruments with off-balance sheet risk of loss.

(g) Leases

The Company determines whether an arrangement is or contains a lease, its classification, and its term at the lease commencement date. Leases with a term greater than one year will be recognized on the balance sheet as right-of-use ("ROU") assets, current lease liabilities, and if applicable, long-term lease liabilities. The Company has elected certain practical expedients permitted under the transition guidance to not record short-term leases (terms less than 12 months). Lease liabilities and the corresponding ROU assets are recorded based on the present values of lease payments over the lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the appropriate incremental borrowing rates, which are the rates that would be incurred to borrow on a collateralized basis, over similar terms, amounts equal to the lease payments in a similar economic environment. Payments for non-lease components or that are variable in nature that do not depend on a rate or index are not included in the lease liability and are typically expensed as incurred. If significant events, changes in circumstances, or other events indicate that the lease term or other inputs have changed, the Company would reassess lease classification, remeasure the lease liability using revised inputs as of the reassessment date, and adjust the ROU assets. Lease expense is recognized on a straight-line basis over the expected lease term for operating-classified leases.

(h) Research and Development Costs

Research and development costs are recorded as expense as incurred and principally consist of contract research organization costs as well as personnel costs, and amounts paid to third parties for up-front and milestone payments made under license and collaboration agreements.

When third-party service providers' billing terms do not coincide with the Company's period-end, the Company is required to make estimates of its obligations to those third parties, including clinical trial costs, contractual services costs and costs for supply of its drug candidates, incurred in a given accounting period and record accruals at the end of the period. The Company bases its estimates on the completion status of the research and development programs and the associated estimate of unbilled costs.

(i) Stock-Based Compensation Expense

The Company measures stock-based awards, including stock options, at their grant-date fair value and records compensation expense over the requisite service period, which is the vesting period of the awards. The Company accounts for forfeitures as they occur.

Estimating the fair value of stock options requires the use of subjective assumptions, including the fair value of the Company's common stock (prior to its initial public offering in January 2024), the expected term of the option and expected stock price volatility. The Company uses the Black-Scholes option-pricing model to value its stock option awards. The assumptions used in calculating the fair value of stock options represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and

management uses different assumptions, stock-based compensation expense could be materially different for future awards.

The fair value of the Company's common stock, prior to its initial public offering, was estimated by the Company's board of directors, with input from management considering the most recently available third-party valuation of the Company's common stock. Subsequent to its initial public offering on January 26, 2024, the fair value of common stock is based on the closing market price of common stock on the date of grant. The expected term of stock options for employees is estimated using the "simplified method," as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. The simplified method is the midpoint between the vesting date and the contractual term of the option. The contractual term is used as the expected term for stock options granted to non-employees. For stock price volatility, the Company uses the implied volatility of its own share trading activity, in addition to comparable public companies as a basis for the expected volatility to calculate the fair value of option grants. The risk-free rate is based on the U.S. Treasury yield curve commensurate with the expected term of the option. The expected dividend yield is zero given the Company does not expect to pay dividends for the foreseeable future.

(j) Net Loss per Share

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period. Pre-funded warrants were included in the denominator as the exercise price is negligible and these warrants are fully vested and exercisable. Diluted net loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock and stock options, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share since when a net loss exists, potentially dilutive securities are not included in the calculation as their impact is anti-dilutive. The Company's convertible preferred stock entitled the holder to participate in dividends and earnings of the Company, and, if the Company had recognized net income, it would have used the two-class method to calculate earnings per share. The two-class method was not applicable during periods with a net loss, as the holders of the convertible preferred stock had no obligation to fund losses.

The following table sets forth the computation of net loss per share, basic and diluted (in thousands, except share and per share data):

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (166,308)	$ (80,488)
Denominator:		
Weighted-average shares of common stock outstanding	37,786,469	—
Weighted-average pre-funded warrants outstanding (1)	676,131	—
Weighted-average shares of common stock outstanding, basic and diluted	38,462,600	31,469,328
Net loss per share attributable to common stockholders, basic and diluted	$ (4.32)	$ (2.56)

(1) Represents the weighted average number of common shares issuable upon the exercise of pre-funded warrants issued in 2025, which are considered to be outstanding for the purposes of the basic and diluted net loss per share calculation from the date of issuance due to their nominal exercise price ($0.0001).

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

	December 31,	
	2025	2024
Stock options	4,328,880	2,531,144
	4,328,880	2,531,144

(k) Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not-to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties. The Company will recognize interest and penalties related to uncertain tax positions as a component of income tax expense (benefit).

(l) Accounting Pronouncements Recently Adopted

In December 2023, the FASB issued ASU 2023-09 *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. This standard includes the requirement that public business entities, on an annual basis, disclose specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5% of the amount computed by multiplying pretax income (or loss) by the applicable statutory income tax rate). It also requires that all entities disclose, on an annual basis, the amount of income taxes paid (net of refunds received) disaggregated by federal, state, and foreign taxes and the amount of income taxes paid (net of refunds received) disaggregated by individual jurisdictions in which income taxes paid (net of refunds received) is equal to or greater than 5% of total income taxes paid (net of refunds received) and requires that all entities disclose income (or loss) from continuing operations before income tax expense (or benefit) disaggregated between domestic and foreign and income tax expense (or benefit) from continuing operations disaggregated by federal, state, and foreign. Lastly, this standard eliminates the requirement for all entities to disclose the nature and estimate of the range of the reasonably possible change in the unrecognized tax benefits balance in the next 12 months or make a statement that an estimate of the range cannot be made. This standard is effective for the Company for the annual period beginning January 1, 2025. Early adoption and retrospective application is permitted. The Company adopted this standard on a prospective basis in the year ended December 31, 2025.

(m) Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03 *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. This standard requires

an entity to disclose on an annual and interim basis, disaggregated information about specific income statement expense categories. It also requires an entity to include certain amounts that are already required to be disclosed under current GAAP in the same disclosure. Additionally, it requires an entity to disclose a qualitative description of the amounts remaining in relevant expense captions that are not separately disaggregated quantitatively, and to disclose the total amount of selling expenses and, in annual reporting periods, an entity's definition of selling expenses. This standard is effective for the Company for the annual period beginning January 1, 2027 and interim periods beginning January 1, 2028. Early adoption is permitted. This standard can be applied prospectively for reporting periods after the effective date or retrospectively to any or all prior periods presented in the financial statements. The Company is currently evaluating the impact that this standard may have on its financial statements.

(n) Reverse Stock Split

On January 23, 2024, the Company filed an amendment to its Certificate of Incorporation and effected a 15.21-for-1 reverse stock split of its issued and outstanding shares of common stock. All common stock share and per-share amounts presented in the financial statements and related notes have been retroactively adjusted to reflect the reverse stock split.

(o) License and Collaboration Agreements

The Company analyzes its license and collaborative agreements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. To the extent the arrangement is within the scope of ASC 808, the Company assesses whether aspects of the arrangement are within the scope of other accounting literature. If the Company concludes that some or all aspects of the arrangement represent a transaction with a customer, it accounts for those aspects of the arrangement within the scope of ASC 606, *Revenue from Contracts with Customers*. None of the license and collaboration agreements discussed in Note 11 represent transactions with customers.

If the Company concludes that some or all aspects of the arrangement are within the scope of ASC 808 and do not represent a transaction with a customer, it recognizes costs incurred as a component of the related expense in the period incurred. The arrangements may also require the Company to make payments on achievement of certain milestones, including clinical, regulatory, and development milestones. Clinical, regulatory, and development milestones are recognized as research and development expense only when such milestones are deemed probable of being achieved.

(p) Other Comprehensive Income (Loss)

Other comprehensive income (loss) ("OCI") consists of expenses, gains, and losses that are excluded from net income under GAAP. The Company's OCI includes, when applicable, unrealized gains and losses on available-for-sale debt securities.

Unrealized gains and losses on available-for-sale debt securities are recorded net of tax in accumulated other comprehensive income (loss) ("AOCI"), a component of stockholders' equity, until realized. Upon realization, these amounts are reclassified from AOCI into earnings.

(4) Fair Value Measurements

The following tables show the Company's cash equivalents and available-for-sale securities' carrying amounts, fair values, and fair value hierarchy as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Level 1	Level 2	Level 3
Money market funds	$ 40,494	$ —	$ —	$ 40,494	$ 40,494	$ —	$ —
Corporate securities	105,373	78	(25)	105,426	16,347	89,079	—
Government securities	161,882	116	(143)	161,855	—	161,855	—
Total assets measured at fair value	$ 307,749	$ 194	$ (168)	$ 307,775	$ 56,841	$ 250,934	$ —

	December 31, 2024						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Level 1	Level 2	Level 3
Money market funds	$ 49,031	$ —	$ —	$ 49,031	$ 49,031	$ —	$ —
Corporate securities	114,577	10	(148)	114,439	—	114,439	—
Government securities	98,150	18	(91)	98,077	—	98,077	—
Total assets measured at fair value	$ 261,758	$ 28	$ (239)	$ 261,547	$ 49,031	$ 212,516	$ —

Cash balances were $5.0 million at each of December 31, 2025 and 2024. Money market funds are highly liquid investments. The pricing information on the Company's money market funds are based on quoted prices in active markets. This approach results in a classification of these securities as Level 1 of the fair value hierarchy.

The Company's investment portfolio includes many fixed income securities that do not always trade on a daily basis. As a result, the pricing services used by the Company applied other available information as applicable through processes such as benchmark yields, benchmarking of like securities, sector groupings and matrix pricing to prepare evaluations. In addition, model processes were used to assess interest rate impact and develop prepayment scenarios. These models take into consideration relevant credit information, perceived market movements, sector news and economic events. The inputs into these models may include benchmark yields, reported trades, broker-dealer quotes, issuer spreads and other relevant data.

As of December 31, 2025, $267.3 million of the Company's fixed income securities have maturity dates within the next twelve months. All securities are considered available for sale. During the year ended December 31, 2025, the Company had proceeds from the sale of available-for-sale marketable securities of $18.9 million.

(5) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2025	2024
Research and development	$ 19,830	$ 7,209
Professional fees	3	233
Insurance	183	174
Tax credit receivable	—	500
Other	60	—
	$ 20,076	$ 8,116

(6) Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2025	2024
Research and development	$ 13,142	$ 8,626
Professional fees	292	474
Compensation and related expenses	6,545	4,163
Other accrued expenses	18	67
	$ 19,997	$ 13,330

(7) Commitments and Contingencies

Leases

The Company has two operating leases that it subleases for its office space in California, one of which commenced in January 2024 with an original lease term through January 2026 (which ended in January 2026). The Company's other lease has an initial lease term of less than twelve months; therefore, it does not recognize this lease as an operating lease on the balance sheet.

Operating lease expense was $0.2 million for each of the years ended December 31, 2025 and 2024. The Company's remaining lease term and discount rate for its operating lease as of December 31, 2025 are 0.08 years and 10.0%, respectively.

Future maturities of operating lease liabilities were as follows as of December 31, 2025 (in thousands):

Fiscal year ending:	
2026	$ 14
2027	—
Total future minimum payments	14
Less imputed interest	—
Present value of lease liabilities	$ 14

Cash paid for rent expense recorded during the years ended December 31, 2025 and 2024 was $0.2 million and $0.2 million, respectively.

Purchase Commitments

The Company enters into contracts in the normal course of business with contract research organizations, contract manufacturing organizations, universities, and other third parties for preclinical research studies, clinical trials and testing and manufacturing services. These contracts generally do not contain minimum purchase commitments and are cancellable by the Company upon prior written notice although, purchase orders for clinical materials are generally non-cancellable. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancellable obligations of the Company's service providers, up to the date of cancellation or upon completion of a manufacturing run.

Employee Benefit Plan

The Company maintains a 401(k) plan for employees. The 401(k) plan qualifies as a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Under the 401(k) plan, participating employees may defer a portion of their pre-tax earnings. The Company contributes 100% of employee salary deferral contributions up to 4% of pay for

each payroll period. The Company contributions to the 401(k) plan during the years ended December 31, 2025 and 2024, were $0.7 million and $0.5 million, respectively.

Contingencies

Liabilities for loss contingencies, arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount of the assessment and/or remediation can be reasonably estimated.

(8) Convertible Preferred Stock and Common Stock

Convertible Preferred Stock

In June 2021, the Company sold 90,000,000 shares of Series A convertible preferred stock ("Series A") at an original issuance price of $1.00 per share. In February 2022, the Company sold 60,000,000 shares of Series A at an original issuance price of $1.00 per share. In December 2022, the Company sold 104,761,894 shares of Series B convertible preferred stock ("Series B") at an original issuance price of $1.05 per share. In March 2023, the Company sold 42,857,140 shares of Series B at an original issuance price of $1.05 per share. The Series A and Series B stock were converted to common stock at the Company's January 2024 initial public offering.

Classification of Convertible Preferred Stock

Prior to their conversion into common stock, the Series A and Series B were classified outside of stockholders' equity (deficit) because the holders of such shares had redemption rights in the event of a Deemed Liquidation Event that was not solely within the control of the Company. Because the occurrence of a Deemed Liquidation Event was never considered probable, the carrying values of the Convertible Preferred Stock were not accreted to their redemption values.

Common Stock

The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders. Unless required by law, there shall be no cumulative voting. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, after the payment of all preferential amounts required to be paid to any holders of shares of Convertible Preferred Stock, the remaining funds and assets available for distribution to the stockholders of the Company will be distributed among the holders of shares of common stock, pro rata based on the number of shares of common stock held by each such holder.

"At-the-Market" Offering

On February 3, 2025, the Company filed an automatic shelf registration statement on Form S-3ASR with the SEC pursuant to which the Company registered for sale an indeterminate amount of any combination of its common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that the Company may determine, which is referred to as the "2025 WKSI Shelf". The 2025 WKSI Shelf includes a prospectus covering up to an aggregate of $250.0 million of shares of common stock that the Company is able to issue and sell from time to time, through Jefferies LLC ("Jefferies"), acting as its sales agent, pursuant to the Open Market Sale Agreement℠, dated February 3, 2025 (the "Sales Agreement"), for its "at-the-market" equity program.

Under the Sales Agreement, Jefferies may sell shares of the Company's common stock by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 of the Securities Act of 1933, as amended, subject to the terms of the Sales Agreement.

During the year ended December 31, 2025, the Company sold 5,560,266 shares of common stock pursuant to the Sales Agreement for total proceeds of $122.2 million, net of commissions and other expenses. As of December 31, 2025, the Company has approximately $123.3 million remaining for future issuances of common stock pursuant to the Sales Agreement.

July Public Offering

On July 3, 2025, the Company closed an underwritten public offering in which the Company issued and sold an aggregate of 3,059,615 shares of its common stock, including the exercise in full of the underwriters' option to purchase 576,923 additional shares of common stock, at a public offering price of $19.50 per share, and, in lieu of shares of common stock to certain investors, pre-funded warrants to purchase up to 1,363,469 shares of common stock at a public offering price of $19.4999 per pre-funded warrant, which represents the per share public offering price for the shares less the $0.0001 per share exercise price for each pre-funded warrant. The pre-funded warrants were recorded as a component of shareholders' equity within additional paid-in-capital and have no expiration date. As of December 31, 2025, none of the pre-funded warrants have been exercised. The proceeds to the Company, net of underwriting discounts, commissions, and other expenses were $80.5 million.

The pre-funded warrants are exercisable at any time after their original issuance. A holder of pre-funded warrants may not exercise the pre-funded warrant if the holder, together with its affiliates, would beneficially own more than 4.99%, or, at the election of such holder upon issuance, 9.99%, of the number of shares of common stock outstanding or more than 4.99%, or, at the election of such holder upon issuance, 9.99%, of the combined voting power of the Company's securities outstanding immediately after giving effect to such exercise. A holder of pre-funded warrants may increase or decrease this percentage to any other percentage not exceeding 19.99%, in the case of an increase, upon 61 days' prior notice to the Company. As of December 31, 2025, there have been no exercises of pre-funded warrants since their issuance.

(9) Stock-based Compensation

In June 2021, the Company adopted the 2021 Employee, Director and Consultant Equity Incentive Plan (as amended, the "2021 Plan"), that authorized the Company to grant up to 803,564 shares of common stock via stock-based compensation awards. In 2022, the Company amended the 2021 Plan and increased the total number of shares authorized under the 2021 Plan to 2,748,818. In January 2024, the Company adopted the 2024 Employee, Director and Consultant Equity Incentive Plan (the "2024 Plan") that authorized the Company to grant up to 3,900,000 shares of common stock plus any remaining ungranted or forfeited shares from the 2021 Plan. As of December 31, 2025, there were 3,504,507 shares available to be granted under the 2024 Plan. The Company's stock options vest based on the terms in the awards agreements and generally vest over four years. The Company recorded stock-based compensation expense in the following expense categories in its accompanying statements of operations and comprehensive loss (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	$ 5,387	$ 1,328
General and administrative	7,133	1,880
	$ 12,520	$ 3,208

The following is a summary of stock options activity:

	Options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2024	2,531,144	$ 6.77		
Granted	2,182,326	25.59		
Exercised	(125,605)	4.01		
Forfeited/Expired	(258,985)	19.68		
Outstanding as of December 31, 2025	4,328,880	15.56	8.16	$ 31,675
Exercisable as of December 31, 2025	1,503,536	5.50	6.91	22,157
Vested and expected to vest at December 31, 2025	4,328,880	$ 15.56	8.16	$ 31,675

The weighted-average grant-date fair value of options granted in 2025 and 2024 were $20.47 and $7.52 per share, respectively. The fair value was estimated using the Black-Scholes option-pricing model based on the following assumptions:

	Year Ended December 31,	
	2025	2024
Risk-free interest rate	3.78% - 4.37%	3.69% - 4.66%
Expected term	5.5 - 6.1 years	5.5 - 6.1 years
Expected volatility	96.1% - 98.3%	93.1% - 98.6%
Expected dividend yield	—	—
Estimated fair value of the Company's common stock per share (a)	$ 18.03 - 27.56	$ 5.85 - 24.58

(a) Subsequent to the initial public offering on January 26, 2024, the fair value of common stock is based on the closing market price of common stock on the date of grant.

Unrecognized compensation cost for awards not vested as of December 31, 2025 was $37.6 million and will be expensed over a weighted-average period of 2.7 years.

(10) Income Taxes

The Company accounts for income taxes under ASC 740. The Company has incurred losses since inception and has not recognized any current or deferred income tax expense for the year ended December 31, 2025. It is more likely than not that the Company's deferred tax assets will not be realized. Accordingly, a full valuation allowance has been recorded against the deferred tax assets. A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before income taxes after the adoption of ASU 2023-09 is as follows (in thousands):

	Year Ended December 31, 2025	
	US Dollars ($)	Rate
Tax at U.S. federal rate	$ (34,927)	21.0 %
Nontaxable/Nondeductible items		
Stock Compensation	1,076	(0.6)
Tax Credits		
Research and Development Credit	(1,989)	1.1
Changes in Valuation Allowances	35,840	(21.5)
Effective tax rate	$ —	— %

Although state income taxes are net zero due to the Company's valuation allowance, Pennsylvania and Maryland made up the majority (greater than 50 percent) of the tax effect in this category. There were no cash tax payments made or refunds received for the year ended December 31, 2025. A reconciliation of the provision for income taxes to the

amount computed by applying the 21% statutory U.S. federal income tax rate to income before income taxes before the adoption of ASU 2023-09 is as follows:

	Year Ended December 31, 2024
Tax at U.S. federal rate	21.0 %
State income taxes	4.9
Other permanent differences	—
Transaction costs	1.1
Rate change	(0.8)
Research and development credit	4.5
Valuation allowance	(30.7)
Total provision	— %

Deferred tax assets and liabilities are determined based on the differences between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which differences are expected to reverse.

Significant components of the Company's deferred tax assets and liabilities consisted of the following (in thousands):

	December 31,	
	2025	2024
Deferred tax assets		
Net operating losses	$ 34,279	$ 16,735
Research and development credit	9,051	7,062
Intangible asset	19,498	9,883
Capitalized research and development	43,805	34,591
Other	2,637	561
Gross deferred tax assets	109,270	68,832
Valuation allowance	(109,270)	(68,793)
Total deferred tax assets	—	39
Deferred tax liabilities		
Right of use asset	—	(39)
Total deferred tax liabilities	—	(39)
Net deferred tax assets and liabilities	$ —	$ —

The Company records a valuation allowance against its net deferred tax asset when it is not more likely than not that such assets will be realized. The realization of deferred tax assets depends upon the Company's ability to generate future taxable income or other tax planning strategies available in the relevant taxing jurisdiction. In evaluating the realizability of its deferred tax assets, Management must determine whether there will be sufficient taxable income to allow for the realization of deferred tax assets. Based upon the historical and anticipated future losses, Management has determined that the deferred tax assets do not meet the more-likely-than-not threshold for realizability. As a result, the Company recorded a valuation allowance against its net deferred tax assets as of December 31, 2025. The valuation allowance increased by $40.4 million and $24.7 million during the year ended December 31, 2025 and 2024, respectively due to the current year pre-tax losses and research and development tax credits.

As of December 31, 2025 and 2024, the Company had federal net operating loss ("NOL") carryforwards of $138.5 million and $67.4 million, which will be carried forward indefinitely to offset future taxable income, subject to an 80 percent limitation of taxable income annually. In addition, as of December 31, 2025 and 2024, state NOLs exist of approximately $121.7 million and $58.8 million subject to various carryforward periods with the first state NOLs beginning to expire in 2043. The Company also had research and development tax credit carryforwards of approximately

$9.1 million and $7.1 million as of December 31, 2025 and 2024. The research credit carryforward will begin to expire in 2041. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOL carryforwards and credits to offset its post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in ownership by one or more "5% shareholders" (as defined under U.S. income tax laws) that exceeds 50 percentage points over a rolling three-year period. Similar rules apply under state tax laws. The Company has not determined if it has experienced Section 382 ownership changes in the past and if a portion of the NOL and tax credit carryforwards are subject to an annual limitation under Section 382. In addition, the Company may experience ownership changes in the future as a result of subsequent shifts in stock ownership, some of which may be outside of our control.

As of December 31, 2025, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's financial statements. The Company is currently subject to U.S. Federal and state tax examination. As a result of tax attribute carryforwards, all U.S. federal and state tax periods from the Company's inception in 2021 through 2025 remain open. The Company does not have a reserve for uncertain tax positions.

(11) License and Collaboration Agreements

Allist

In June 2021, the Company entered into a Global Technology Transfer and License Agreement with Allist ("Allist Agreement"). Pursuant to the Allist Agreement, the Company was granted an exclusive license under certain intellectual property to develop, manufacture and commercialize certain licensed products in the field in the licensed territory. Upon execution of the Allist Agreement, the Company paid Allist a non-refundable cash payment of $40.0 million and issued 1,276,250 shares of its common stock. The upfront payment and the fair value of the common stock issued was recorded to research and development expense in 2021.

Upon the achievement of certain clinical, regulatory and commercial milestones using the licensed technology, the Company is obligated to make future milestone payments to Allist of up to $105.0 million in clinical and regulatory milestones and up to $655.0 million in commercial milestones. Furthermore, royalties, ranging from high single digit to low mid-teen percentages will be payable to Allist on net sales of licensed products in licensed territories.

In connection with the Allist Agreement, in December 2021, the parties also entered into a Joint Clinical Collaboration Agreement ("Clinical Collaboration") to define the framework under which the parties will cooperate and share costs related to global clinical studies to be conducted jointly by the Company and Allist. During the years ended December 31, 2025 and 2024, the Company incurred $0.6 million and $0.9 million, respectively, in cost reimbursements to Allist under the Clinical Collaboration which have been recorded as research and development expense. The Company also received cost reimbursements from Allist of $1.4 million and $0.3 million for the years ended December 31, 2025 and 2024, respectively, which has been recorded as a reduction of research and development expenses. The Company incurred $5.0 million in clinical milestone payments to Allist during the year ended December 31, 2025. During the year ended December 31, 2025, no additional milestones were met, achieved, or were probable of achievement.

Alphamab

In June 2024, the Company entered into a collaboration agreement with Jiangsu Alphamab Biopharmaceuticals Co., Ltd. ("Alphamab") to discover, develop and commercialize novel antibody drug conjugates ("ADCs") for the treatment of cancers ("Alphamab Agreement").

Under the Alphamab Agreement, both companies seek to leverage Alphamab's proprietary linker-payload platform and glycan-conjugation technology to identify novel ADCs for oncology indications. The Alphamab Agreement gives

the Company exclusive rights to develop and commercialize ADCs globally, except greater China, which includes mainland China, Hong Kong, Macau and Taiwan where Alphamab retains the right to develop and commercialize the ADCs.

The terms of the Alphamab Agreement include combined upfront and potential milestone payments to Alphamab of up to $201.5 million based on the achievement of certain regulatory and development milestones, and up to $414.0 million based on the achievement of certain commercial milestones. In addition, Alphamab is entitled to receive tiered sales royalties, ranging from low single digit to mid-single digit percentages, from the Company for net sales of each ADC product.

The upfront payment was recorded to research and development expense during the year ended December 31, 2024. During the years ended December 31, 2025 and 2024, the Company paid $4.6 million and $0.2 million in cost reimbursements, respectively, to Alphamab under the Alphamab Agreement. $1.7 million of these payments were expensed in the year ended December 31, 2025, also as research and development. Finally, during the year ended December 31, 2025, the Company paid $1.2 million upon the approval of a target pair selection, which was also included in research and development expense. During the year ended December 31, 2025, no additional milestones were met, achieved, or were probable of achievement.

Aarvik

In December 2021, the Company entered into a Research Collaboration Agreement, as amended, effective June 30, 2023 (the "Aarvik Collaboration Agreement"), with Aarvik Pharmaceuticals, Inc. ("Aarvik"), under which the Company is required to pay Aarvik up to $3.1 million on statements of work ("SOWs") and an initiation fee of $0.3 million. After the completion of the SOWs, the Company has an exclusive option to license the Aarvik intellectual property, and the option to acquire certain of Aarvik's intellectual property, after which it is the Company's sole responsibility to research, develop, manufacture and commercialize any applicable compound and product in the field and territory. In August 2024, the Company paid $1.0 million to exercise that option, and as a result is now obligated to pay up to $18.0 million per product upon the achievement of certain clinical and regulatory milestone events and up to $80.0 million per product in commercial milestones. Additionally, the Company is obligated to pay Aarvik royalties in the mid-single digits based on net sales of licensed products.

On August 9, 2024, the Company entered into an amendment and restatement of the Aarvik Collaboration Agreement (the "Amended and Restated Aarvik Collaboration Agreement"). Under the Amended and Restated Aarvik Collaboration Agreement, Aarvik granted the Company an exclusive option to obtain exclusive rights to certain of Aarvik's intellectual property for the research, development, manufacture, use, commercialization, or other exploitation of the ADCs related to (i) the two agreed targets to which the compounds being developed under the collaboration bind, which is referred to as the Target Pair, and (ii) the acquisition of exclusive rights to certain intellectual property generated during the collaboration. The Company has not yet selected the indication or indications that it would pursue in the collaboration and anticipates doing so in connection with the identification of a lead candidate for IND-enabling activities. Under the Amended and Restated Aarvik Collaboration Agreement, the Company has paid Aarvik a collaboration initiation fee and research fees as provided in the SOWs in an aggregate amount of $4.9 million.

The Company incurred $0.5 million and $2.3 million in research and development expenses related to the Aarvik SOWs during the years ended December 31, 2025 and 2024, respectively. No milestones have been met or achieved, or are probable of achievement, since the inception of the Aarvik Collaboration Agreement.

Lepu

On January 21, 2025, the Company entered into an Exclusive License Agreement (the "Lepu Biopharma Agreement") with Lepu Biopharma Co., Ltd. ("Lepu"), pursuant to which Lepu granted the Company a right to develop and commercialize ARR-217, an antibody drug conjugate for gastrointestinal cancers outside Greater China.

Under the Lepu Biopharma Agreement, Lepu granted to the Company: (i) an exclusive, royalty-bearing, sublicensable license under certain intellectual property owned or controlled by Lepu, to develop, manufacture and

commercialize any product containing ARR-217 for all uses in all countries and territories other than Greater China (as defined in the Lepu Biopharma Agreement) (the "ArriVent Territory"); and (ii) a non-exclusive license under certain intellectual property controlled by Lepu to develop, manufacture and commercialize any product containing ARR-217 for use in oncology in the ArriVent Territory. Under the Lepu Biopharma Agreement, the Company paid Lepu a one-time upfront payment of $40 million and, during the three months ended June 30, 2025, the Company paid $1.0 million to Lepu for the achievement of the first developmental milestone under the Lepu Biopharma Agreement as it became probable of achievement during the second quarter. Lepu is eligible to receive a potential near-term clinical milestone payment for $6.0 million in cash. The upfront payment was included in research and development expenses. Finally, Lepu is eligible to receive payments of up to $0.3 billion in development and regulatory milestones, and up to $0.89 billion in commercial milestones, and tiered royalties in high single-digit to low-teen percentages on net sales in the ArriVent Territory.

Other than the milestone payment of $1.0 million recorded in the second quarter of 2025, no milestones have been met or achieved, or are probable of achievement, since the inception of the Lepu Biopharma Agreement. During year ended December 31, 2025, the Company paid $1.7 million in research and development expenses related to the Lepu Biopharma Agreement.

(12) Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources in assessing performance. The Company has one reportable segment: life science. The life science segment is engaged in identifying, licensing and globalizing top biopharma innovations from around the world to deliver important medicines to patients. The Company's chief operating decision maker ("CODM") is the chief executive officer.

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

To date, the Company has not generated any product revenue. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval.

As such, the CODM uses cash forecast models in deciding how to invest into the life science segment. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss is used to monitor budget versus actual results. Monitoring budgeted versus actual results is used in assessing performance of the segment, establishing cash forecast models and to optimize the distribution of resources across functions, therapeutic areas and research and development programs.

The table below summarizes the significant expense categories regularly provided to the CODM for the years ended December 31, 2025 and 2024:

(in thousands)	Year Ended December 31, 2025	2024
Operating expenses:		
Research and development: Firmonertinib (excluding personnel-related and other internal costs):		
FURTHER	$ 9,838	$ 12,272
FURVENT	48,741	34,135
FAVOUR	397	272
Other Firmonertinib costs	8,634	4,187
Total Firmonertinib	67,610	50,865
Research and development: Early-stage programs	55,470	10,940
Research and development: Personnel-related and other internal costs	30,271	17,199
General and administrative: Personnel-related costs	15,404	8,153
General and administrative: Other costs	8,779	7,151
Other segment items (a)	(11,226)	(13,820)
Net loss	$ (166,308)	$ (80,488)

(a) Other segment items is comprised of interest and investment income.

(13) Debt

On May 8, 2025, the Company entered into a Loan and Security Agreement (the "Loan Agreement") between the Company and Silicon Valley Bank, a Division of First-Citizens Bank & Trust Company (the "Bank"), pursuant to which, the Bank agreed to extend up to $75.0 million to the Company (the "Term Loan"), consisting of: (i) a first tranche commitment of $35.0 million to be drawn at the Company's option, subject to the satisfaction of certain conditions, (ii) a second tranche commitment of up to $15.0 million to be drawn at the Company's option, subject to the satisfaction of certain conditions, and (iii) at the Company's option, subject to the satisfaction of certain conditions, a third tranche commitment of $25.0 million. If not drawn, each tranche commitment is subject to an expiration date. In March 2026, the Company entered into an amendment of the Loan Agreement in which one of the conditions of the second tranche commitment was eliminated. No amounts have been drawn on this Term Loan as of December 31, 2025.

The Term Loan matures on March 1, 2030 (or, if the Company does not satisfy certain conditions, on March 1, 2029) unless otherwise accelerated following the occurrence and continuation of an event of default pursuant to the terms of the Loan Agreement. Amounts borrowed under the Term Loan bear interest at a variable annual rate equal to the greater of (i) 6.00%, and (ii) (A) the Prime Rate, minus (B) 0.75%. The Company may, at their option, prepay the Term Loan subject to a prepayment premium.

The Company's obligations are secured by a first priority, perfected lien on substantially all the property and assets of the Company, except for intellectual property (other than the security interest in proceeds from any intellectual property) and certain other customary excluded assets as set forth therein.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of December 31, 2025, we conducted an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of the end of the period covered by this Annual Report on Form 10-K.

Inherent Limitations over Internal Controls

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive officer and principal financial officer, or persons performing similar functions, and effected by a company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of a company's assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that a company's receipts and expenditures are being made only in accordance with authorizations of the company's management and directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is

designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States.

Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2025, using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (2013). We have evaluated the effectiveness of our internal control over financial reporting as of the end of the period covered by this Annual Report on Form 10-K, with the participation of our Chief Executive Officer and Chief Financial Officer, as well as other key members of our management. Based on this assessment, management concluded that, as of December 31, 2025, the Company's internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include, and is not required to include, an attestation report of our registered public accounting firm. Additionally, our independent registered public accounting firm will not be required to opine on our internal control over financial reporting until we are no longer an emerging growth company.

Changes in Internal Control Over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any changes in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. There were no changes in our internal control over financial reporting during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Rule 10b5-1 Trading Plans

During the fiscal year ended December 31, 2025, none of our directors or executive officers adopted, modified or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any “non-Rule 10b5-1 trading arrangement” as defined in Item 408(c) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Management and Corporate Governance," "Delinquent Section 16(a) Reports," "Corporate Code of Conduct" and "Insider Trading Policies" in our Proxy Statement for the 2026 Annual Meeting of Stockholders expected to be held on June 18, 2026.

Item 11. Executive Compensation

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Management and Corporate Governance" in our Proxy Statement for the 2026 Annual Meeting of Stockholders expected to be held on June 18, 2026.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement for the 2026 Annual Meeting of Stockholders expected to be held on June 18, 2026.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Certain Relationships and Related Person Transactions" and "Management and Corporate Governance – Director Independence" in our Proxy Statement for the 2026 Annual Meeting of Stockholders expected to be held on June 18, 2026.

Item 14. Principal Accountant Fees and Services

The response to this item is incorporated by reference from the discussion responsive thereto in the proposal entitled "Selection of Independent Registered Public Accounting Firm" in our Proxy Statement for the 2026 Annual Meeting of the Stockholders expected to be held on June18, 2026.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The financial statements filed as part of this Annual Report are listed in the Index to Financial Statements. Certain schedules are omitted because they are not applicable, or not required, or because the required information is included in the financial statements or notes thereto. The Exhibits are listed in Item 15 (b) below.

(b) Exhibit Index.

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-41929) filed with the SEC on January 30, 2024).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No. 001-41929) filed with the SEC on January 30, 2024).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024).
4.2	Amended and Restated Investors' Rights Agreement, dated as of December 16, 2022 (incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024).
4.3	Description of Securities (incorporated by reference to Exhibit 4.3 of the Registrant's Annual Report on Form 10-K (File No. 001-41929) filed on March 28, 2024).
	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K (File No. 001-41929) filed on July 2, 2025).
10.1	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024).
10.2+	2021 Employee, Director and Consultant Equity Incentive Plan, as amended and form of stock option agreement thereunder (incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024)
10.3+	2024 Employee, Director and Consultant Equity Incentive Plan, form of stock option agreement and form of restricted stock agreement thereunder (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1/A (File No. 333-276397) filed on January 22, 2024).
10.4+	ArriVent BioPharma, Inc. Executive Severance Plan (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024).
10.5+	Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-41929) filed on November 10, 2025).
10.6+	Offer Letter Agreement, by and between the Registrant and Zhengbin (Bing) Yao, Ph.D., dated May 5, 2021 (incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024).
10.7+	Offer Letter Agreement, by and between the Registrant and Stuart Lutzker, M.D., Ph.D., dated May 1, 2021 (incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024).

Exhibit Number	Description of Exhibit
10.8+	Offer Letter Agreement, by and between the Registrant and Robin LaChapelle, dated May 21, 2021 (incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024).
10.9+	Offer Letter Agreement, by and between the Registrant and James Kastenmayer, J.D., Ph.D., dated August 11, 2023 (incorporated by reference to Exhibit 10.10 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024).
10.10+	Offer Letter Agreement, by and between the Registrant and Winston Kung, MBA, dated January 3, 2024 (incorporated by reference to Exhibit 10.11 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024).
10.11#	License Agreement, by and between the Registrant and Shanghai Allist Pharmaceuticals Co., Ltd., dated June 29, 2021, as amended by Amendment No. 1, dated November 6, 2023 (incorporated by reference to Exhibit 10.12 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024).
10.12#	Joint Clinical Collaboration Agreement, by and between the Registrant and Shanghai Allist Pharmaceuticals Co., Ltd., dated December 24, 2021 (incorporated by reference to Exhibit 10.13 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024).
10.13#	Amended and Restated Research Collaboration Agreement, by and between the Registrant and Aarvik Therapeutics, Inc., dated August 9, 2024 (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-41929) filed on November 14, 2024).
10.14#	Amendment No. 1 to the Amended and Restated Research Collaboration Agreement, by and between the Registrant and Aarvik Therapeutics, Inc., dated July 2, 2025 (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-41929) filed on November 10, 2025).
10.15#	Clinical Collaboration Agreement, by and between the Registrant and Beijing InnoCare Pharma Tech Co., Ltd., dated June 23, 2023 (incorporated by reference to Exhibit 10.15 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024).
10.16#	Research and Collaboration Agreement, by and between the Registrant and Jiangsu Alphamab Biopharmaceuticals Co., Ltd, dated June 2, 2024 (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-41929) filed on August 14, 2024).
10.17	Open Market Sale AgreementSM, by and between Jefferies LLC and the Registrant, dated February 3, 2025 (incorporated by reference to Exhibit 1.2 of the Registrant's Registration Statement on Form S-3 (File No. 333-284661) filed with the SEC on February 3, 2025).
10.18#	Exclusive License Agreement, dated January 21, 2025, by and between Lepu Biopharma Co., Ltd and the Registrant (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-41929) filed on May 12, 2025).
10.19	Loan and Security Agreement, dated May 8, 2025, by and between Silicon Valley Bank, a Division of First-Citizens Bank & Trust Company, and the Registrant (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-41929) filed on August 11, 2025).
16	Letter from KPMG LLP, dated March 13, 2025 (incorporated by reference to Exhibit 16.1 of the Registrant's Current Report on Form 8-K (File No. 001-41929) filed on March 13, 2025.
19	Insider Trading Policy. (incorporated by reference to Exhibit 19 of the Registrant's Annual Report on Form 10-K (File No. 001-41929) filed on March 3, 2025.

Exhibit Number	Description of Exhibit
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024).
23.1*	Consent of PricewaterhouseCoopers LLP.
23.2*	Consent of KPMG LLP.
24.1*	Power of Attorney (included on signature page).
31.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-15(e) or Rule 15d-15(e) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-15(e) or Rule 15d-15(e) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32**	Certification of Chief Executive Officer and Chief Financial Officer of Periodic Report Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1+	ArriVent BioPharma, Inc. Clawback Policy (incorporated by reference to Exhibit 10.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-276397) filed on January 5, 2024).
101.INS	Inline XBRL Instance Document-the Instance Document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

* Filed with this Annual Report on Form 10-K.

** The Certifications attached as Exhibit 32 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of ArriVent BioPharma, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

\+ Denotes management compensation plan or contract.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

ARRIVENT BIOPHARMA, INC.

Date: March 5, 2026

By: /s/ Zhengbin (Bing) Yao, Ph.D.
Zhengbin (Bing) Yao, Ph.D.
Chairman, President and Chief Executive Officer

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Zhengbin (Bing) Yao, Ph.D. and Winston Kung, MBA, and each of them, with full power of substitution and resubstitution and full power to act without the other, as their respective true and lawful attorney-in-fact and agent to act in their respective name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated:

Signature	Title	Date
/s/ Zhengbin (Bing) Yao, Ph.D. Zhengbin (Bing) Yao, Ph.D.	Chairman, Chief Executive Officer and Director *(Principal Executive Officer)*	March 5, 2026
/s/ Winston Kung, MBA Winston Kung, MBA	Chief Financial Officer and Treasurer *(Principal Accounting Officer and Principal Financial Officer)*	March 5, 2026
/s/ Merdad Parsey, M.D., Ph.D. Merdad Parsey, M.D., Ph.D.	Director	March 5, 2026
/s/ James Healy, M.D., Ph.D. James Healy, M.D., Ph.D.	Director	March 5, 2026
/s/ John Hohneker, M.D. John Hohneker, M.D.	Director	March 5, 2026
/s/ Stuart Lutzker, M.D., Ph.D. Stuart Lutzker, M.D., Ph.D.	President of Research and Development and Director	March 5, 2026
/s/ Chris W. Nolet Chris W. Nolet	Director	March 5, 2026
/s/ Kristine Peterson Kristine Peterson	Director	March 5, 2026

Corporate Information

Board of Directors

Zhengbin (Bing) Yao, Ph.D., Chairman
President and Chief Executive Officer of ArriVent BioPharma, Inc.

Kristine Peterson
Former Chief Executive Officer of Valeritas, Inc.

James Healy, M.D., Ph.D.
General Partner at Sofinnova Investments, Inc.

John Hohneker, M.D.
Former President and Chief Executive Officer of Anokion SA

Stuart Lutzker, M.D., Ph.D.
President, R&D of ArriVent BioPharma, Inc.

Chris Nolet
Former Audit Partner at Ernst & Young LLP

Merdad Parsey, M.D., Ph.D.
Former Executive Vice President and Chief Medical Officer of Gilead Sciences, Inc.

Executive Officers

Zhengbin (Bing) Yao, Ph.D.
President and Chief Executive Officer

Stuart Lutzker, M.D., Ph.D.
President, R&D

Robin LaChapelle
Chief Operating Officer

Winston Kung
Chief Financial Officer

James Kastenmayer
General Counsel

Shareholder Information

Stockholders and Stock Listing
Our common stock is traded on Nasdaq Global Market under the symbol AVBP. On April 24, 2026, the closing price of our common stock was $30.42 per share and our common stock was held by 69 stockholders of record.

Investor Information
You may obtain a copy of any of the exhibits to our Annual Report on Form 10-K free of charge. These documents are available on our website at https://arrivent.com/ or by contacting Investor Relations department at (628) 277-4836. Requests for information about ArriVent BioPharma, Inc. should be directed to our Investor Relations department.

Annual Meeting
Our 2026 Annual Meeting of Stockholders will be held on Thursday, June 18, 2026, at 12:00 p.m., Eastern Time, via live webcast on the Internet at the following URL:
www.virtualshareholdermeeting.com/AVBP2026

Internet Website
https://arrivent.com/

Independent Registered Public Accounting Firm
PricewaterhouseCoopers LLP
Philadelphia, Pennsylvania

Transfer Agent and Registrar
Transfer Agent and Registrar
Computershare Trust Company, N.A.
150 Royall Street
Canton, MA 02021