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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

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 001-39219

Revolution Medicines, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**47-2029180**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
700 Saginaw Drive **Redwood City, CA**	**94063**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 481-6801

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	RVMD	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)
Warrants to purchase 0.1112 shares of common stock expiring 2026	RVMDW	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

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

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐No ☒

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

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 as of June 30, 2024 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately $6.5 billion, based on the closing price of the Registrant's common stock, as reported by the Nasdaq Global Select Market on June 30, 2024 of $38.81 per share.

The number of shares of the Registrant's Common Stock outstanding on the Nasdaq Global Select Market as of February 21, 2025 was 185,913,326 (excluding 2,173,917 shares underlying pre-funded warrants).

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement relating to the Registrant's 2025 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. The proxy statement will be filed with the Securities and Exchange Commission within 120 days of the Registrant's fiscal year ended December 31, 2024.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be 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 terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the scope, progress, results and costs of developing our product candidates or any other future product candidates, and conducting preclinical studies and clinical trials;
- the scope, progress, results and costs related to the research and development of our pipeline;
- the timing of and costs involved in obtaining and maintaining regulatory approval for any of current or future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- our expectations regarding the potential market size and size of the potential patient populations for our product candidates and any future product candidates, if approved for commercial use;
- our ability to maintain and establish new collaborations, licensing or other arrangements and the financial terms of any such agreements;
- our commercialization, marketing and manufacturing capabilities and expectations;
- the rate and degree of market acceptance of our product candidates, as well as the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model and strategic plans for our business, product candidates and technology, including additional indications for which we may pursue;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates, including the projected term of patent protection;
- our expectations regarding our ability to obtain, maintain, enforce and defend our intellectual property protection for our product candidates;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- developments and projections relating to our competitors and our industry, including competing therapies and procedures;
- regulatory and legal developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- our ability to attract and retain key scientific or management personnel; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

We have based these forward-looking statements largely on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any

forward-looking statements contained herein until after we distribute this Annual Report on Form 10-K, whether as a result of any new information, future events or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

Investors and others should note that we may announce material business and financial information to our investors using our investor relations website (ir.revmed.com), Securities and Exchange Commission (SEC) filings, webcasts, press releases and conference calls. We use these mediums, including our website, to communicate with our members and public about our company, our products and other issues. It is possible that the information that we make available may be deemed to be material information. We therefore encourage investors and others interested in our company to review the information that we make available on our website.

Summary of Material Risks Associated with Our Business

The principal risks and uncertainties affecting our business include the following:

- We are a clinical-stage precision oncology company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability, which, together with our limited operating history, makes it difficult to assess our future viability.
- We have never generated revenue from product sales and may never be profitable.
- We will require substantial additional financing to achieve our goals, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- Our business is dependent on the successful development of our current and future product candidates. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any of our product candidates, or we experience significant delays in doing so, our business will be materially harmed.
- Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which would have an adverse effect on our business.
- Historically, direct inhibition of any RAS protein has been challenging due to a lack of tractable, or "druggable," binding pockets. Given this approach is unproven, it may not be successful.
- The results of preclinical studies and early-stage clinical trials may not be predictive of future results.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise be adversely affected.
- We and our collaborators are currently developing and may in the future develop, our product candidates in combination with other therapies, which exposes us to additional risks.
- We face significant competition, and if our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.
- If we and our collaborators are unable to obtain and maintain sufficient patent and other intellectual property protection for our product candidates and technology, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any of our current or future product candidates.

The summary risk factors described above should be read together with the text of the full risk factors below in the section entitled "Risk Factors" and the other information set forth in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially and adversely affect our business, competitive position, financial condition, results of operations, cash flows and growth prospects.

PART I

Item 1. Business.

Overview

We are a clinical-stage precision oncology company developing novel targeted therapies for RAS-addicted cancers. We possess sophisticated structure-based drug discovery capabilities built upon deep chemical biology and cancer pharmacology know-how and innovative, proprietary technologies that enable the creation of small molecules tailored to unconventional binding sites. Guided by our understanding of genetic drivers and adaptive resistance mechanisms in cancer, we deploy precision medicine approaches to inform innovative monotherapy and combination regimens.

Our research and development pipeline comprises RAS(ON) inhibitors that bind directly to RAS variants, which we refer to as RAS(ON) Inhibitors, and RAS companion inhibitors that target key nodes in the RAS pathway or associated pathways. Our RAS(ON) Inhibitors are designed to be used as monotherapy, in combination with other RAS(ON) Inhibitors and/or in combination with RAS companion inhibitors or other therapeutic agents.

RAS(ON) Inhibitors

Our RAS(ON) Inhibitors are based on our proprietary tri-complex technology platform, which enables a highly differentiated approach to inhibiting the active, GTP-bound form of RAS, which we refer to as RAS(ON). We are developing a portfolio of compounds that we believe were the first RAS(ON) Inhibitors to use this mechanism of action. We believe that direct inhibitors of RAS(ON) suppress cell growth and survival and are less susceptible to adaptive resistance mechanisms recognized for RAS(OFF) inhibitors.

We are evaluating our RAS(ON) Inhibitors alone and in combination with other drugs and investigational drug candidates, particularly in-pathway agents. We believe tailored RAS(ON) Inhibitors will be useful to serve the diverse landscape of RAS-addicted cancers optimally. We believe that in some cases, patients may experience maximal clinical benefit from the broad activity of our RAS(ON) multi-selective inhibitor, daraxonrasib (RMC-6236), if approved. In others, we believe treatment with a RAS(ON) mutant-selective inhibitor may be optimal. We further believe that in some cases, it could be beneficial to combine daraxonrasib with a RAS(ON) mutant-selective inhibitor, with daraxonrasib functioning as the backbone of these RAS(ON) Inhibitor doublets. In addition, we believe that in some cases, combination of our RAS(ON) Inhibitors with standard of care therapies, including immunotherapies, may be optimal.

We are advancing a deep pipeline of RAS(ON) Inhibitors, including daraxonrasib (RMC-6236), our RAS(ON) multi-selective inhibitor; elironrasib (RMC-6291), our G12C-selective inhibitor; and zoldonrasib (RMC-9805), our G12D-selective inhibitor. Together, we consider these three clinical-stage candidates as the first wave of RAS(ON) inhibitors that we are advancing through clinical development. We also currently plan to advance RMC-5127 (G12V) into clinical development. In addition, we have other preclinical-stage RAS(ON) inhibitor clinical development opportunities, including the RAS(ON) mutant-selective inhibitors RMC-0708 (Q61H) and RMC-8839 (G13C).

Daraxonrasib (RMC-6236)

Daraxonrasib (RMC-6236), our RAS(ON) multi-selective inhibitor, is designed as an oral, RAS-selective tri-complex inhibitor of multiple RAS(ON) variants containing cancer driver mutations at all three of the major RAS mutation hotspot positions (G12, G13 and Q61). Daraxonrasib inhibits all three major RAS isoforms, suppressing the mutant cancer driver and cooperating wild-type RAS proteins.

A global, randomized Phase 3 registrational trial of daraxonrasib in the second-line (2L) treatment of patients with metastatic pancreatic ductal adenocarcinoma (PDAC), which we call the RASolute 302 study, is ongoing. In the RASolute 302 study, we are randomizing patients in a 1:1 ratio to receive either daraxonrasib at a dose of 300 mg daily or the investigator's choice of chemotherapy. The RASolute 302 study has a nested trial design allowing for a hierarchical sequence of statistical analysis, with patients with tumors harboring RAS G12X mutations serving as the core population which will be tested first and all enrolled patients serving as the secondary population. We believe this nested design and hierarchical testing increases the probability of trial success based on the core population while creating an opportunity to gain approval for a broader population. Patients in the RASolute 302 study will be evaluated for the dual primary endpoints of progression-free survival (PFS) and overall survival (OS) in the core population, with secondary endpoints including PFS and OS in the secondary population and objective response rate (ORR) and quality of life measures. We currently expect to substantially complete enrollment of the RASolute 302 study in 2025, to enable an expected clinical readout in 2026.

Having finalized the study protocol, we are now activating sites for a global, randomized Phase 3 registrational trial comparing daraxonrasib versus docetaxel in patients with locally advanced or metastatic RAS-mutated non-small cell lung cancer (NSCLC) who have been treated with immunotherapy and platinum-containing chemotherapy, which we call the RASolve 301 study. In the RASolve 301 study, we are randomizing patients in a 1:1 ratio to receive either daraxonrasib or docetaxel. The RASolve 301 study has a nested trial design allowing for a hierarchical sequence of statistical analysis, with patients with tumors harboring RAS G12X (other than G12C) mutations serving as the core population which will be tested first, and all enrolled patients serving as the secondary population. We believe this nested design and hierarchical testing increases the probability of trial success based on the core population while creating an opportunity to gain approval for a broader population. Patients in the RASolve 301 study will be evaluated for the dual primary endpoints of PFS and OS in the core population, with secondary endpoints including PFS and OS in the secondary population and ORR and quality of life measures.

We currently expect to initiate a global, randomized Phase 3 daraxonrasib monotherapy study in patients with first-line (1L) metastatic PDAC in the second half of 2025. We also currently expect to initiate a global, randomized Phase 3 monotherapy study of daraxonrasib as adjuvant treatment for patients with resectable PDAC in the second half of 2025.

On December 2, 2024 we reported updated clinical safety, tolerability, and activity data for daraxonrasib from our first-in-human monotherapy study of daraxonrasib, which we refer to as the RMC-6236-001 study, in patients with previously treated RAS-mutant PDAC as of a data cutoff date of July 23, 2024. We believe these data showed that daraxonrasib was generally well tolerated and demonstrated encouraging antitumor activity that supported our initiation of the RASolute 302 study.

Also on December 2, 2024, we reported clinical safety and tolerability data as of a September 30, 2024 data cutoff date for daraxonrasib from the RMC-6236-001 study in patients with NSCLC with tumors harboring RAS mutations. We also reported clinical activity data as of a September 30, 2024 data cutoff date for daraxonrasib from the RMC-6236-001 study in patients with NSCLC with tumors harboring RAS G12X mutations who had received one or two prior lines of therapy which must have included prior immunotherapy and platinum chemotherapy administered either concurrently or sequentially, but not docetaxel, a study population matching the planned RASolve 301 enrollees. We believe these data showed that daraxonrasib was generally well tolerated and demonstrated encouraging antitumor activity that supported our initiation of the RASolve 301 study.

Based on our observations from the RMC-6236-001 study and our preclinical observations, we believe there is a potential opportunity to evaluate daraxonrasib combinations in earlier lines of therapy in multiple tumor types, and we are currently evaluating several exploratory combination regimens that include daraxonrasib in order to assess the potential for development in these settings. These combinations include daraxonrasib with pembrolizumab, daraxonrasib with elironrasib, daraxonrasib with zoldonrasib and daraxonrasib with standard of care chemotherapy agents.

On December 2, 2024, we disclosed initial clinical safety and tolerability data as of a data cutoff date of October 28, 2024 from our clinical study of the combination of daraxonrasib with pembrolizumab, which we believe showed the combination was generally well tolerated with limited hepatotoxicity.

Also on December 2, 2024, we disclosed initial clinical safety, tolerability and activity data as of a data cutoff date of October 28, 2024 from our clinical study of the combination of daraxonrasib with elironrasib, which we believe showed the combination was generally well tolerated and provide initial proof-of-mechanism for a RAS(ON) inhibitor doublet in patients with colorectal cancer (CRC) who were previously treated with KRAS(OFF) G12C inhibitors. We believe these preliminary data observations support continued development of RAS(ON) inhibitor doublets in a broad range of tumor types and earlier lines of therapy, including 1L patients with NSCLC carrying RAS G12C tumors.

In April 2024, at the American Association for Cancer Research (AACR) Annual Meeting 2024, we reported individual case studies from the RMC-6236-001 study that showed examples of objective responses to daraxonrasib in patients with tumor types beyond PDAC or NSCLC, specifically patients with melanoma and with CRC.

Elironrasib (RMC-6291)

Elironrasib (RMC-6291) is designed as a RAS(ON) oral tri-complex G12C-selective inhibitor. It is designed to exhibit subnanomolar potency for suppressing RAS pathway signaling and growth of RAS G12C-bearing cancer cells and is engineered to be highly selective for RAS G12C over wild-type RAS and other cellular targets. Elironrasib is designed to be differentiated from first-generation KRAS(OFF) G12C inhibitors, which sequester the KRAS(OFF) G12C form, by its mechanism of directly inhibiting the RAS(ON) G12C form.

On October 13, 2023, we reported interim preliminary safety and anti-tumor data from our ongoing first-in-human study of elironrasib, which we refer to as the RMC-6291-001 study, as of an October 5, 2023 data cut-off date, which we believe provide preliminary evidence of clinically meaningful differentiation of elironrasib from KRAS(OFF) G12C inhibitors.

We are evaluating several exploratory combination regimens that include elironrasib in order to assess the potential for development in earlier lines of therapy. These combinations include elironrasib with pembrolizumab and, as discussed in the "*Daraxonrasib (RMC-6236*)" section above, elironrasib with daraxonrasib. We are also planning a combination study of elironrasib with both daraxonrasib and pembrolizumab.

On December 2, 2024, we disclosed initial clinical safety, tolerability and activity data for the combination of daraxonrasib with elironrasib, as discussed in the "*Daraxonrasib (RMC-6236*)" section above.

Also on December 2, 2024, we disclosed clinical safety and tolerability data as of a data cutoff date of October 28, 2024 for the combination of elironrasib with pembrolizumab, which we believe showed the combination was generally well tolerated with limited hepatotoxicity.

Zoldonrasib (RMC-9805)

Zoldonrasib (RMC-9805) is designed as a RAS(ON) oral tri-complex G12D-selective inhibitor. It is designed to exhibit low nanomolar potency for suppressing RAS pathway signaling and growth of RAS G12D-bearing cancer cells and is engineered to covalently inactivate RAS G12D irreversibly.

On October 25, 2024, we reported preliminary clinical safety, tolerability and activity data as of a data cutoff date of September 2, 2024 from our first-in-human monotherapy study of zoldonrasib, which we refer to as the RMC-9805-001 study in patients with previously treated solid tumors harboring KRAS G12D mutations.

We believe that these data support our ongoing development of zoldonrasib as a single agent and in combination with other therapies, including with daraxonrasib. An exploratory combination study of zoldonrasib with daraxonrasib is ongoing. We currently expect to disclose additional zoldonrasib clinical safety and antitumor activity data in the second quarter of 2025.

We currently expect to initiate one or more pivotal combination studies in 2026 that incorporate either zoldonrasib or elironrasib and currently expect to share clinical data supporting these plans in the second or third quarter of 2025.

RMC-5127

RMC-5127 is designed as a RAS(ON) oral G12V-selective inhibitor. It is designed to exhibit picomolar potency for suppressing RAS pathway signaling and growth of RAS G12V-bearing cancer cells and is engineered for selective inhibition of RAS G12V over other RAS isoforms via non-covalent binding interactions. We currently expect to advance RMC-5127 to a clinic-ready stage in 2025 and to initiate a first-in-human dose escalation clinical trial of RMC-5127 in 2026.

RMC-0708

RMC-0708 is designed as a RAS(ON) oral Q61H-selective inhibitor. It is designed to exhibit picomolar potency for suppressing RAS pathway signaling and growth of RAS Q61H-bearing cancer cells and is engineered for selective inhibition of RAS Q61H over other RAS isoforms via non-covalent binding interactions. Clinical development of RMC-0708 is subject to our continuing assessment of our portfolio priorities.

RMC-8839

RMC-8839 is designed as a RAS(ON) oral G13C-selective inhibitor. It is designed to exhibit picomolar potency for suppressing RAS pathway signaling and growth of KRAS G13C-bearing cancer cells and is engineered to covalently inactivate KRAS G13C for irreversible inhibition. Clinical development of RMC-8839 is subject to our continuing assessment of our portfolio priorities.

Other Development Opportunities

We have developed RAS companion inhibitors that are designed to suppress cooperating targets and pathways that sustain RAS-addicted cancers. These compounds include RMC-4630, which is designed as a potent and selective inhibitor of SHP2; RMC-5552, which is designed as a selective inhibitor of mTORC1 signaling in tumors; and RMC-5845, which is designed to target SOS1 a protein

that plays a key role in converting RAS(OFF) to RAS(ON) in cells. Additional clinical development of our RAS companion inhibitors is subject to our continuing assessment of our portfolio priorities.

We are also developing preclinical next-generation programs that are designed to sustain our innovation platform beyond our current development-stage assets.

Our Strategy

Overview

Our goal is to revolutionize treatment for patients with RAS-addicted cancers through the discovery, development and delivery of innovative, targeted medicines. RAS proteins drive a significant number of human cancers, and are largely unserved by targeted therapeutics. The KRAS G12C mutation has been clinically validated as a therapeutic target, and the evidence is strong that numerous other oncogenic mutations in the RAS family of proteins are likewise compelling cancer targets. Our collection of RAS(ON) Inhibitors is tailored to target RAS mutations that together comprise the driver mutations in the vast majority of RAS-addicted cancers.

Our RAS(ON) Inhibitors are unique in that they are the first RAS inhibitors in clinical development to specifically target the activated, or ON, form of oncogenic RAS proteins. This differentiated mechanism of action offers potential improvements over that of the first RAS inhibitors to gain U.S. Food and Drug Administration (FDA) approval (KRAS G12C inhibitors sotorasib and adagrasib), which interact exclusively with the OFF form. Based on an emerging understanding of the limitations of first-generation RAS(OFF) drugs in the clinic and findings from our own preclinical research, we believe our RAS(ON) Inhibitors have the potential to deliver deeper antitumor activity and more durable clinical benefit to a broader patient population.

Our pipeline of RAS(ON) multi-selective and RAS(ON) mutant-selective inhibitors offer an opportunity for RAS(ON) doublet combinations designed to potentially maximize durable clinical benefit by effectively targeting the most common KRAS mutant variants in cancer. The consistent finding from the first-generation mutant-selective RAS inhibitors is that the main resistance mechanism that curtails durable efficacy is through reactivation of RAS pathway, highlighting the oncogenic addiction in RAS-mutated cancers. We believe many of these resistance mechanisms may be amenable to inhibition with a RAS(ON) multi-selective inhibitor. The pairing of the RAS(ON) multi-selective inhibitor daraxonrasib with a mutant-selective inhibitor (such as elironrasib or zoldonrasib) may address potential resistances which may ultimately translate to more durable clinical benefit. In addition, our experiments have shown that two inhibitors generally result in more effective inhibition of the primary mutant RAS driver than either inhibitor alone. These doublets form a core part of our strategy to improve the standard of care for patients with RAS-addicted cancers, along with monotherapy and combination with standard of care therapies. This approach is based on our biological understanding of RAS addiction and leverages the unique nature of our pipeline.

Our current corporate priorities are to:

- Execute pivotal trials with daraxonrasib monotherapy in patients with previously treated metastatic PDAC and NSCLC.
- Advance daraxonrasib into earlier-line randomized pivotal trials in patients with PDAC.
- Generate sufficient data to inform development priorities for elironrasib and zoldonrasib and prepare to initiate one or more pivotal trials including these compounds either as monotherapy or in a drug combination.
- Progress our earlier-stage pipeline, including advancing next-generation innovations from the company’s highly productive discovery organization.
- Grow our commercial and operational capabilities and increase precommercial activities in support of a potential commercial launch.

RAS Mutant Epidemiology in the United States.

Variants in RAS proteins account for a significant number of human cancers in the United States, many of which are fatal. Diverse oncogenic RAS variants in three different RAS isoforms (KRAS, NRAS and HRAS) drive distinct human cancers. Based on tumor mutation frequencies from Foundation Medicine data, scaled to estimated patient numbers using cancer incidence from the American Cancer Society (ACS) Cancer Facts and Figures 2023, there are estimated to be more than 200,000 RAS-mutant cancer diagnoses each year in the United States, including approximately 60,000 NSCLC diagnoses (approximately 30% of NSCLC diagnoses), approximately 75,000 CRC diagnoses (approximately 50% of CRC diagnoses) and approximately 56,000 PDAC diagnoses (more than 90% of PDAC diagnoses).

Our Innovation Engine

We have built an innovation engine that enables us to discover and develop novel targeted therapies for elusive high-value frontier cancer targets with a particular focus on a cohesive set of disease targets within notorious growth and survival pathways. This engine is centered around our proprietary tri-complex platform and is bolstered by three complementary pillars:

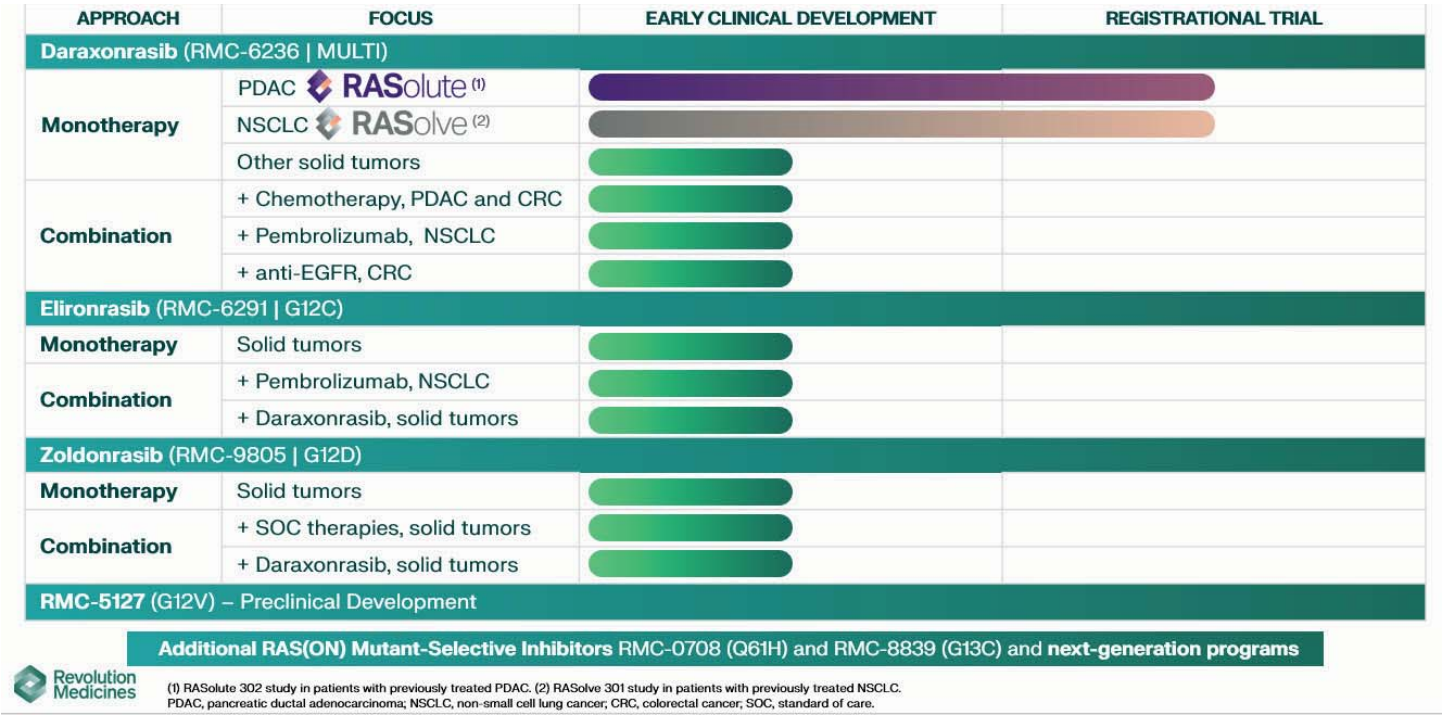
- Deep chemical biology and cancer pharmacology know-how, including assays and proprietary tool compounds, to define the critical vulnerabilities of "frontier" RAS and related pathway targets, associated signaling circuits in cancer cells and immune system targets;
- Sophisticated structure-based drug discovery capabilities, including proven access to complex chemical space, to create drug candidates tailored to unconventional binding sites on elusive cancer targets; and
- Astute precision medicine approach, embracing patient selection and innovative single agent and combination drug regimens, to translate our preclinical insights into clinical benefit for patients with RAS-addicted cancers.

Our Tri-Complex Platform

Our proprietary tri-complex technology enables us to discover small molecule inhibitors of targets lacking intrinsic drug binding sites by inducing new druggable pockets. This occurs through small molecule-driven formation of a high affinity ternary complex (tri-complex) between the target protein, the small molecule, and a widely expressed cytosolic protein called a chaperone (e.g., cyclophilin A or FKPB12). This platform technology is the foundation of our RAS(ON) Inhibitor programs. In this context, the inhibitory effect of tri-complex formation on the RAS(ON) target is mediated by steric occlusion of the site where RAS(ON) binds its downstream effector molecules, such as RAF, which are required for propagating the oncogenic signal. Thus, tri-complex formation with RAS(ON) targets disrupts RAS effector binding and terminates oncogenic signaling. Our RAS(ON) tri-complex inhibitors, which are inspired by natural products, are "Beyond Rule of 5" compounds.

Pipeline

Our pipeline is summarized below:



RAS(ON) Inhibitor Data

Daraxonrasib (RMC-6236)

Daraxonrasib (RMC-6236), our RAS(ON) multi-selective inhibitor, is designed as a potent, oral, RAS-selective tri-complex inhibitor of multiple RAS(ON) variants including cancer drivers at all three of the major mutation hotspot positions, G12, G13, and Q61.

Daraxonrasib inhibits all three major RAS isoforms, suppressing the mutant cancer driver and cooperating wild-type RAS proteins. Daraxonrasib is being evaluated in the RMC-6236-001 study, an ongoing monotherapy dose-escalation Phase 1/1b clinical study in patients with KRAS G12-mutated tumors, focused on NSCLC, PDAC and CRC.

Daraxonrasib PDAC Monotherapy

On October 23, 2024 we reported updated clinical safety, tolerability, and activity data for daraxonrasib at a dose levels ranging from 160 mg daily to 300 mg daily, from the RMC-6236-001 study in patients with previously treated RAS-mutant PDAC as of a data cutoff date of July 23, 2024 (the PDAC Data Cutoff Date). Daraxonrasib was generally well tolerated in these patients. As of the PDAC Data Cutoff Date, the median PFS for these patients treated with daraxonrasib in the 2L setting with tumors harboring KRAS G12X mutations was 8.5 months (95% confidence interval (CI): 5.3 – 11.7 months), and the median OS was 14.5 months (95% CI: 8.8 months, not estimable (NE)).

On December 2, 2024 we reported updated clinical safety, tolerability, and activity data for daraxonrasib at a dose level of 300 mg daily, from the RMC-6236-001 study in patients with previously treated RAS-mutant PDAC as of the PDAC Data Cutoff Date.

In the RMC-6236-001 study, a total of 76 patients with PDAC treated with a dose of 300 mg of daraxonrasib daily were evaluated for safety and tolerability as of the PDAC Data Cutoff Date (Table 1). The most common treatment-related adverse events (TRAEs) that were observed were rash and gastrointestinal (GI)-related toxicities. One Grade 4 TRAE (platelet count decreased) was observed, and no Grade 5 TRAEs were observed.

Table 1. RMC-6236-001: TRAEs and TRAEs leading to dose modifications in patients with PDAC treated with daraxonrasib at 300 mg daily

	(N=76)	
Maximum Severity of TRAEs	**Any Grade**	**Grade ≥3**
Any TRAE	73 (96%)	26 (34%)
TRAEs occurring in≥10% of patients, n (%)		
Rash[1]	69 (91%)	6 (8%)
Diarrhea	40 (53%)	3 (4%)
Nausea[2]	29 (38%)	0 (0%)
Vomiting[2]	27 (36%)	0 (0%)
Stomatitis	26 (34%)	3 (4%)
Mucosal inflammation	13 (17%)	1 (1%)
Fatigue	12 (16%)	1 (1%)
Decreased appetite	10 (13%)	0 (0%)
Paronychia	10 (13%)	0 (0%)
Oedema peripheral	10 (13%)	0 (0%)
Platelet count decreased	8 (11%)	3 (4%)
Dry skin	8 (11%)	0 (0%)
Other select TRAEs, n (%)		
Anemia	6 (8%)	5 (7%)
ALT increased	5 (7%)	3 (4%)
Neutrophil count decreased	5 (7%)	2 (3%)
AST increased	4 (5%)	1 (1%)
TRAEs leading to dose modification, n (%)	32 (42%)	
Dose interruption	30 (40%)	
Dose reduction	19 (25%)	
TRAEs leading to dose discontinuation, n (%)	0 (0%)	
Specific TRAEs leading to dose reduction in >10% patients, n (%)		
Rash[3]	10 (13%)	
Mean dose intensity	89%	

Data Cutoff Date of July 23, 2024

[1] Includes preferred terms of dermatitis, dermatitis acneiform, eczema, erythema, rash, rash erythematous, rash maculopapular, rash pruritic and rash pustular; multiple types of rash may have occurred in the same patient.

[2] No prophylaxis for nausea or vomiting was administered.

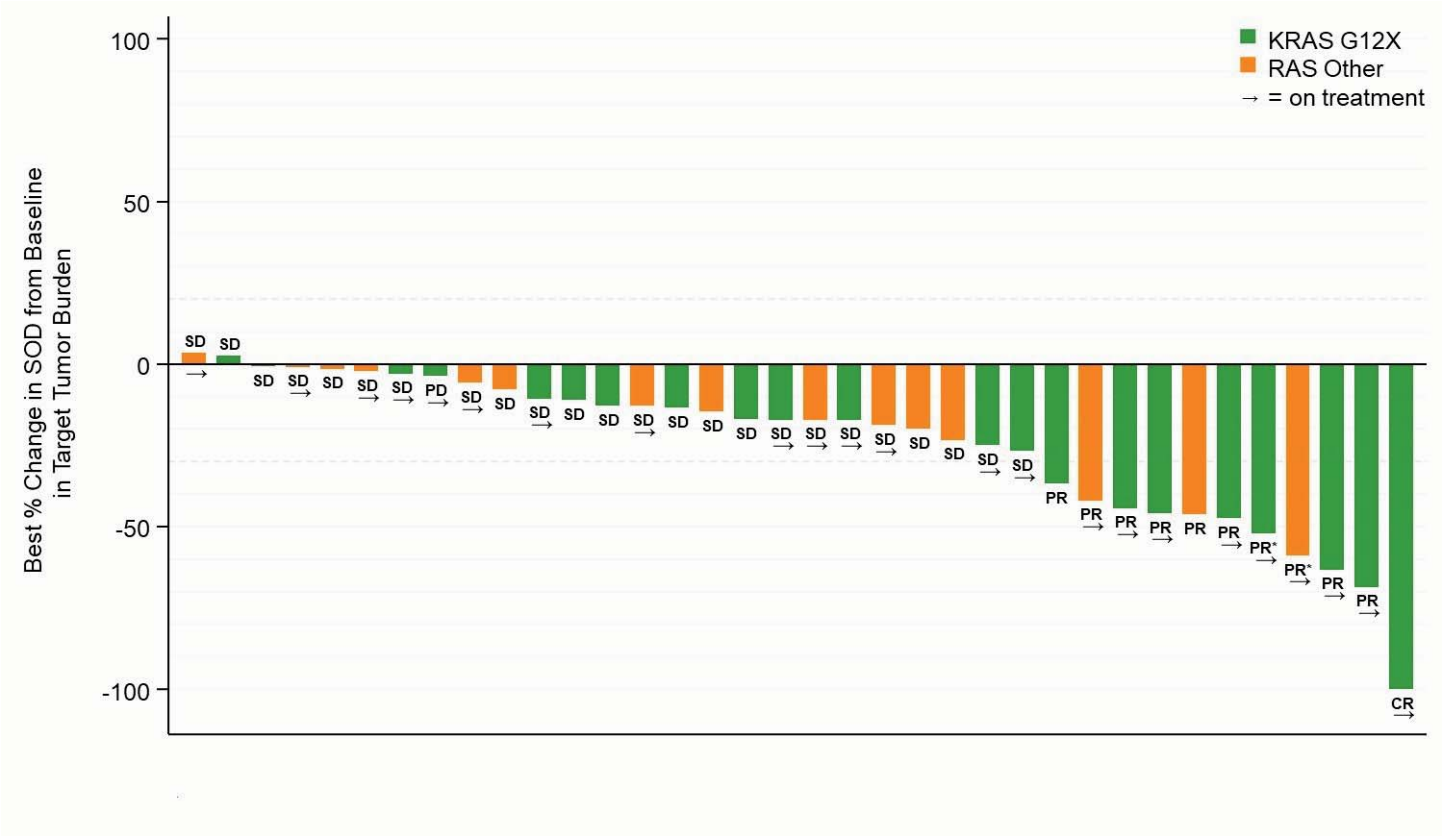
[3] Includes preferred terms of dermatitis acneiform, rash, and rash maculopapular.

Median duration of treatment was 5.2 months.

ALT, alanine transaminase; AST, aspartate transferase.

We also reported best percentage change in tumor size from baseline for patients with metastatic PDAC with tumors harboring KRAS G12X mutations treated with a dose of 300 mg daily in the 2L setting as of the PDAC Data Cutoff Date (Figure 1). The ORR for patients who received the first dose of daraxonrasib at least 14 weeks prior to the PDAC Data Cutoff Date was 36% (8 of 22 patients) for patients with tumors harboring KRAS G12X mutations and was 27% (10 of 37 patients) for patients with tumors harboring G12X, G13X or Q61X mutations.

Figure 1. RMC-6236-001: Best percentage change in tumor size from baseline in patients with PDAC treated in the 2L setting with daraxonrasib at 300 mg daily



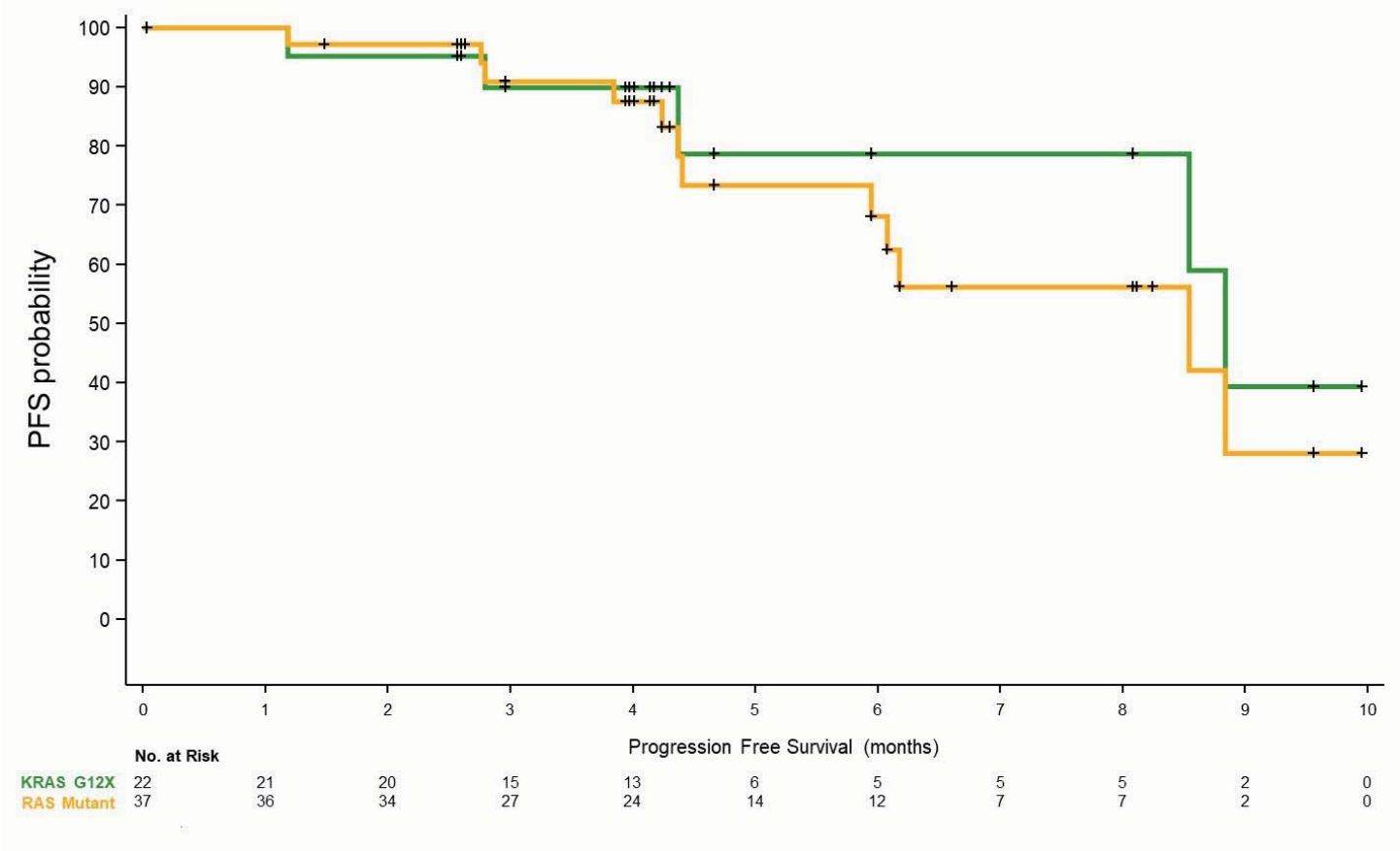
Data Cutoff Date of July 23, 2024

KRAS G12X mutation includes any KRAS mutation where glycine (G) at position 12 is substituted by another amino acid. RAS Other includes mutations in KRAS G13X, KRAS Q61X or mutations in HRAS or NRAS at codons G12X, G13X or Q16X. Among patients with a response (confirmed or unconfirmed), 46% of first response occurred within 2 months of RMC-6236 treatment. 2L in the metastatic setting includes patients who progressed on prior therapy in an earlier setting within 6 months of last dose. ORR analyses included all patients who received first dose of daraxonrasib at least 14 weeks prior to the PDAC Data Cutoff Date (to allow 2 potential scans). Unconfirmed PRs (PR*) with treatment discontinued (will never confirm) were not considered responders but remained in the denominator; ORR (by RECIST v1.1) included confirmed CRs/PRs and unconfirmed CRs/PRs who were still on treatment and may yet be confirmed. One patient included in the denominator of the ORR analyses is not displayed on waterfall due to lack of post-baseline target lesion assessment (patient withdrew consent).

CR, complete response; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease; SOD, sum of diameters.

In addition, we reported preliminary PFS data as of the PDAC Data Cutoff Date for patients with metastatic PDAC treated with a dose of 300 mg daily in the 2L setting (Figure 2). As of the PDAC Data Cutoff Date, the median PFS for patients with tumors harboring KRAS G12X mutations was 8.8 months (95% CI: 8.5, NE), and for patients with tumors harboring G12X, G13X or Q61X mutations was 8.5 months (95% CI: 5.9, NE).

Figure 2. RMC-6236-001: Interim PFS in 2L metastatic PDAC patients treated with daraxonrasib at 300 mg daily



Data Cutoff Date of July 23, 2024

RAS Mutant defined as patients with G12X, G13X or Q61X PDAC.

2L in the metastatic setting includes patients who progressed on prior therapy in an earlier setting within 6 months of last dose.

Median follow-up is 6.1 months and 6.6 months for KRAS G12X and RAS Mutant in the 2L setting at 300 mg, respectively.

We also reported preliminary OS data as of the PDAC Data Cutoff Date for patients with metastatic PDAC treated with a dose of 300 mg daily in the 2L setting (Figure 3). The median OS as of the PDAC Data Cutoff Date for patients with tumors harboring KRAS G12X mutations was not estimable (95% CI: NE, NE) and for patients with tumors harboring G12X, G13X or Q61X mutations was also not estimable (95% CI: 8.5 months, NE). As of the PDAC Data Cutoff Date, the OS rate at 6 months was 100% (95% CI: 100%, 100%) for patients with tumors harboring KRAS G12X mutations and was 97% (95% CI: 79%, 100%) for patients with tumors harboring G12X, G13X or Q61X mutations.

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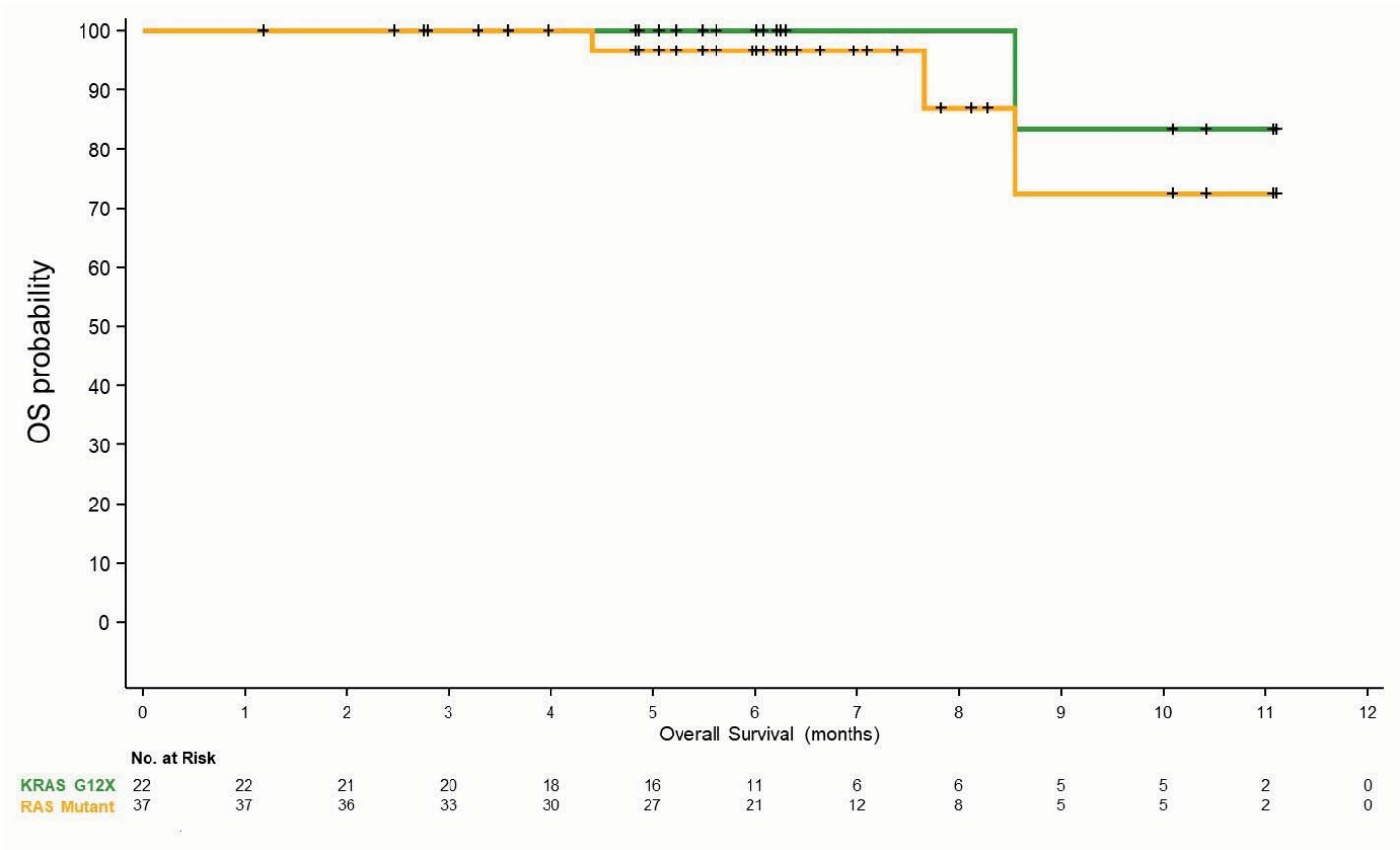
Figure 3. RMC-6236-001: Interim OS in 2L PDAC patients treated with daraxonrasib at 300 mg daily



Data Cutoff Date of July 23, 2024

RAS Mutant defined as patients with G12X, G13X or Q61X PDAC.

2L in the metastatic setting includes patients who progressed on prior therapy in an earlier setting within 6 months of last dose.

Median follow-up is 6.1 months and 6.6 months for KRAS G12X and RAS Mutant, respectively.

OS rate at 6 months and 95% CI are from Kaplan-Meier analysis.

Daraxonrasib NSCLC Monotherapy

On December 2, 2024, we also reported updated clinical safety, tolerability, and activity data for daraxonrasib from the RMC-6236-001 study, as of a data cutoff date of September 30, 2024 (the NSCLC Data Cutoff Date) in patients with RAS-mutant NSCLC.

In the RMC-6236-001 study, a total of 124 patients with NSCLC treated across dose cohorts ranging from 120 mg daily to 300 mg daily were evaluated for safety and tolerability as of the NSCLC Data Cutoff Date (Table 2). We believe that these data show that daraxonrasib was generally well tolerated at dose levels between 120 mg daily and 220 mg daily, with an increase in the rate of TRAEs observed at the 300 mg daily dose level. One Grade 4 TRAE (pneumonitis) was observed at the 300 mg daily dose level. No Grade 5 TRAEs were observed. We also reported the TRAEs leading to dose modifications for patients with NSCLC treated across dose cohorts ranging from 120 mg daily to 300 mg daily as of the NSCLC Data Cutoff Date. For patients treated across dose cohorts ranging from 120 mg daily to 220 mg daily, the median treatment duration was 5.5 months, and the median cumulative duration of dose interruption was 8.5 days.

Table 2. RMC-6236-001: TRAEs and TRAEs leading to dose modifications in patients with NSCLC treated with daraxonrasib across dose cohorts ranging from 120 mg daily to 300 mg daily

	120 mg to 300 mg (N=124)		120-220 mg (N = 73)		300 mg (N = 51)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Any TRAE	121 (98%)	33 (27%)	71 (97%)	12 (16%)	50 (98%)	21 (41%)
TRAEs occurring in ≥10% of patients, n (%)						
Rash[1]	110 (89%)	9 (7%)	66 (90%)	5 (7%)	44 (86%)	4 (8%)
Diarrhea	87 (70%)	10 (8%)	46 (63%)	1 (1%)	41 (80%)	9 (18%)
Nausea	68 (55%)	0 (0%)	36 (49%)	0 (0%)	32 (63%)	0 (0%)
Vomiting	55 (44%)	3 (2%)	29 (40%)	2 (3%)	26 (51%)	1 (2%)
Stomatitis	47 (38%)	3 (2%)	25 (34%)	0 (0%)	22 (43%)	3 (6%)
Paronychia	26 (21%)	0 (0%)	14 (19%)	0 (0%)	12 (24%)	0 (0%)
Fatigue	20 (16%)	0 (0%)	8 (11%)	0 (0%)	12 (24%)	0 (0%)
Dry skin	19 (15%)	0 (0%)	9 (12%)	0 (0%)	10 (20%)	0 (0%)
AST increased	17 (14%)	2 (2%)	11 (15%)	0 (0%)	6 (12%)	2 (4%)
ALT increased	15 (12%)	3 (2%)	10 (14%)	0 (0%)	5 (10%)	3 (6%)
Decreased appetite	14 (11%)	0 (0%)	4 (6%)	0 (0%)	10 (20%)	0 (0%)
Dysgeusia	12 (10%)	0 (0%)	3 (4%)	0 (0%)	9 (18%)	0 (0%)
Other select TRAEs, n (%)						
Anemia	9 (7%)	3 (2%)	4 (6%)	2 (3%)	5 (10%)	1 (2%)
TRAEs leading to dose modification, n (%)	64 (52%)		30 (41%)		34 (67%)	
Dose interruption	59 (48%)		25 (34%)		34 (67%)	
Dose reduction	34 (27%)		15 (21%)		19 (37%)	
TRAEs leading to dose discontinuation, n (%)	7 (6%)		3 (4%)		4 (8%)	
TRAEs leading to dose reductions in ≥ 10% patients, n (%)						
Diarrhea	12 (10%)		4 (6%)		8 (16%)	
Rash[1]	13 (11%)		6 (8%)		7 (14%)	
Mucositis/stomatitis	6 (5%)		1 (1%)		5 (10%)	
Mean dose intensity	81%		88%		72%	

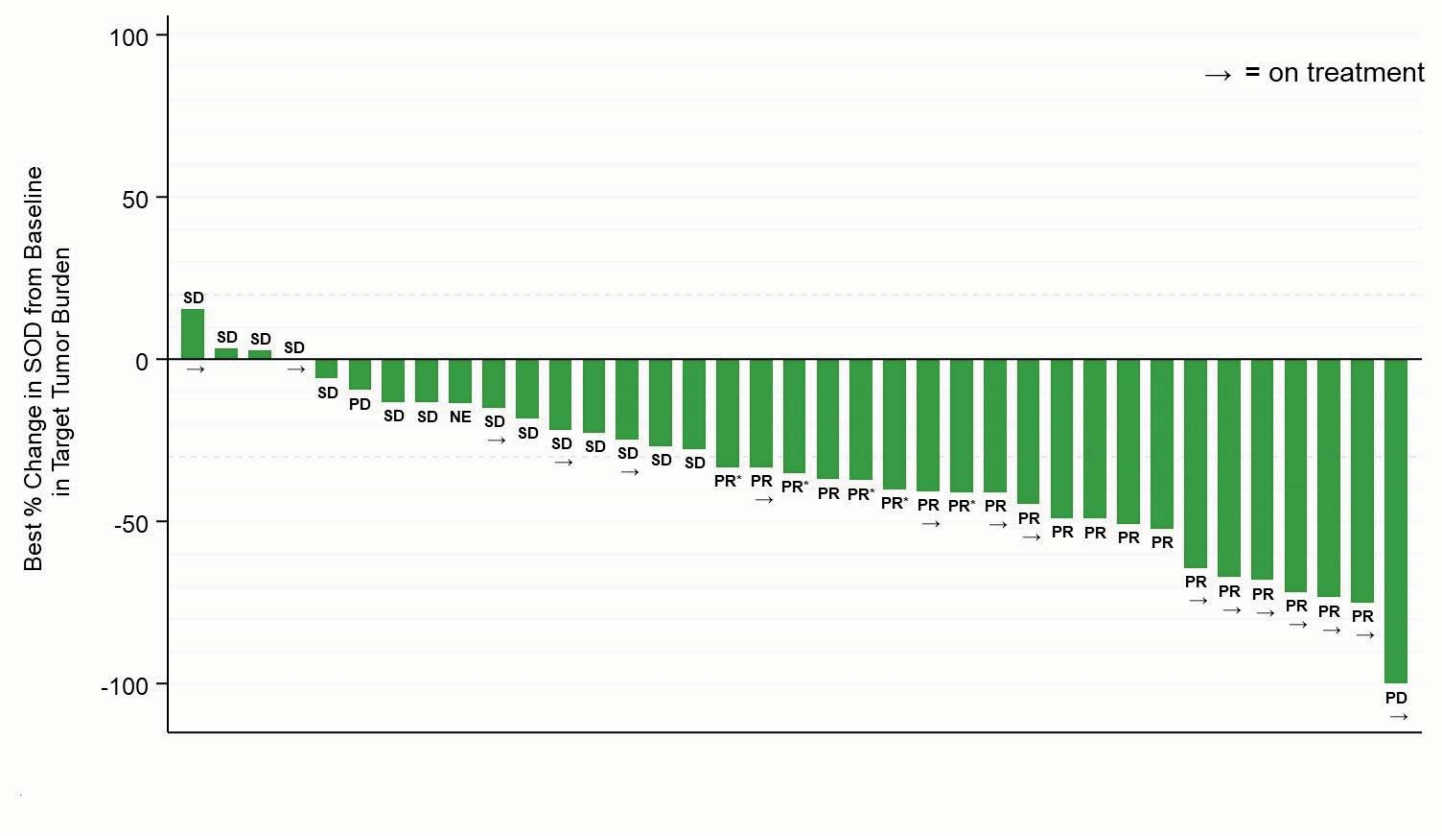
Data Cutoff Date of September 30, 2024

One Grade 4 pneumonitis (possibly related) observed at 300 mg daily dose level in patient with concomitant pneumocystis pneumonia. No other Grade 4 TRAEs were observed. No Grade 5 TRAEs were observed.

[1] Includes preferred terms of rash pustular, rash papular, rash maculopapular, rash macular, rash, erythema, and dermatitis acneiform. Multiple types of rash may have occurred in the same patient.

We also reported best percentage change in tumor size from baseline for patients with NSCLC with tumors harboring RAS G12X mutations who had received one or two prior lines of therapy, which must have included prior immunotherapy and platinum chemotherapy administered either concurrently or sequentially, but did not include docetaxel, who were treated with RMC-6236 across dose cohorts ranging from 120 mg daily to 220 mg daily (NSCLC Efficacy-Evaluable Patients) (Figure 4). The ORR for NSCLC Efficacy-Evaluable Patients who received the first dose of RMC-6236 at least 14 weeks prior to the NSCLC Data Cutoff Date was 38% (15 of 40 patients).

Figure 4. RMC-6236-001: Best percentage change in tumor size from baseline in NSCLC Efficacy-Evaluable Patients



Data Cutoff Date of September 30, 2024

Population includes patients with RAS G12X mutant NSCLC who have received 1 or 2 prior lines of therapy, which must have included prior immunotherapy and platinum chemotherapy administered either concurrently or sequentially, and have not received docetaxel previously. Adjuvant therapy or multimodal therapy with curative intent is considered prior therapy if disease progression occurred or treatment completion was within 6 months of first dose of daraxonrasib.

Among patients with a response (confirmed or unconfirmed), 65% of first response occurred within 2 months of daraxonrasib treatment.

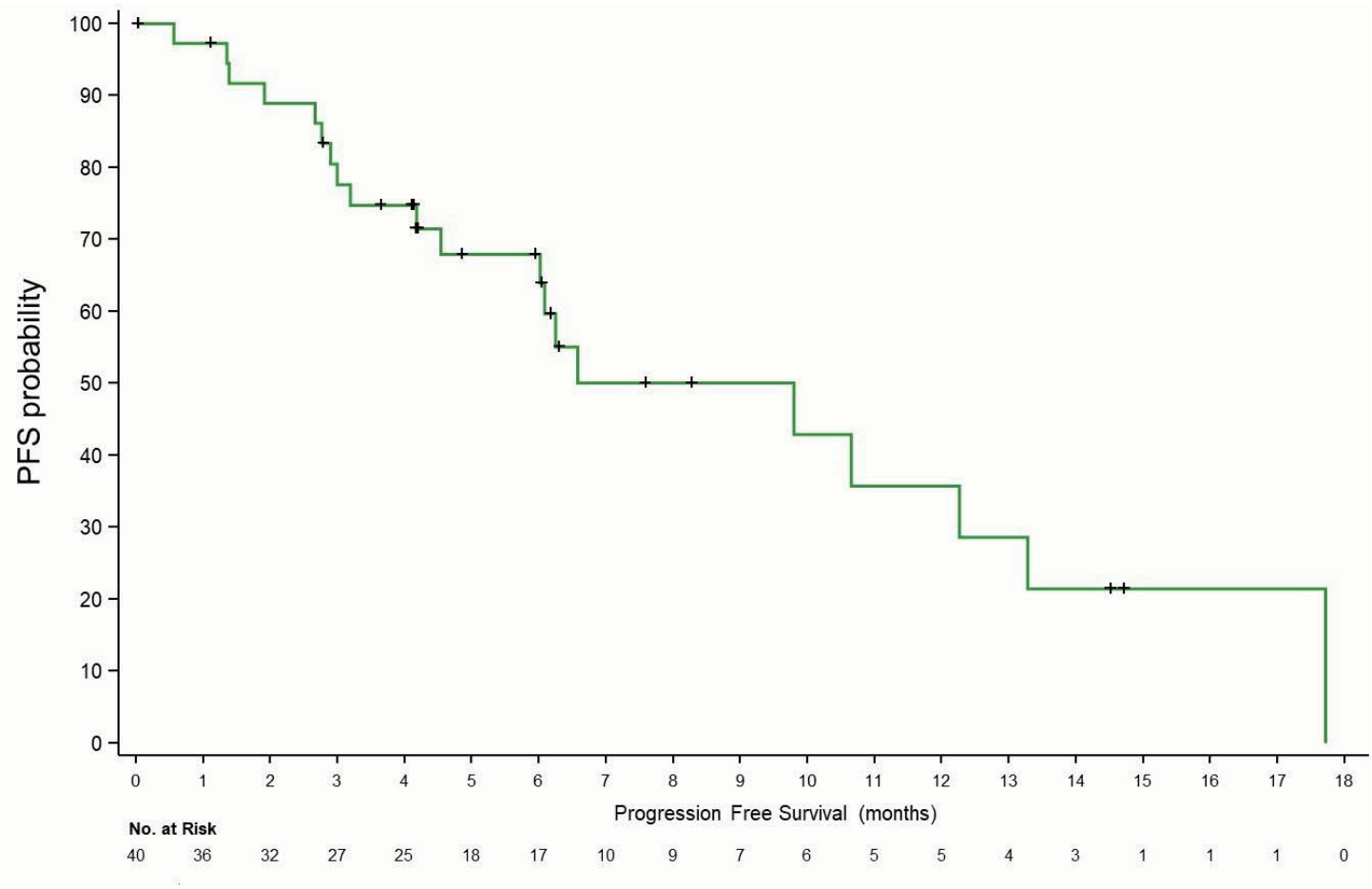
ORR analyses included all patients who received first dose of daraxonrasib at least 14 weeks prior to data cutoff date (to allow 2 potential scans).

ORR (by RECIST v1.1) included confirmed CRs/PRs and unconfirmed CRs/PRs who were still on treatment and may yet be confirmed; unconfirmed PRs (PR*) with treatment discontinued (will never confirm) were not considered responders but remained in the denominator. Three patients included in the denominator of the ORR analyses are not displayed on waterfall due to lack of post-baseline target lesion assessment (2 due to patient request to withdraw from treatment, and 1 due to patient withdrawal of consent); patient with 100% reduction in SOD from baseline was deemed as PD due to new lesion, treatment is ongoing post progression.

CR, complete response; NE, not evaluable; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease; SOD, sum of diameter; DCR, disease control rate.

In addition, we reported preliminary PFS data as of the NSCLC Data Cutoff Date for NSCLC-Evaluable Patients (Figure 5). As of the NSCLC Data Cutoff Date, the median PFS for NSCLC Efficacy-Evaluable Patients was 9.8 months (95% CI: 6.0, 12.3).

Figure 5. RMC-6236-001: Interim PFS in NSCLC Efficacy-Evaluable Patients



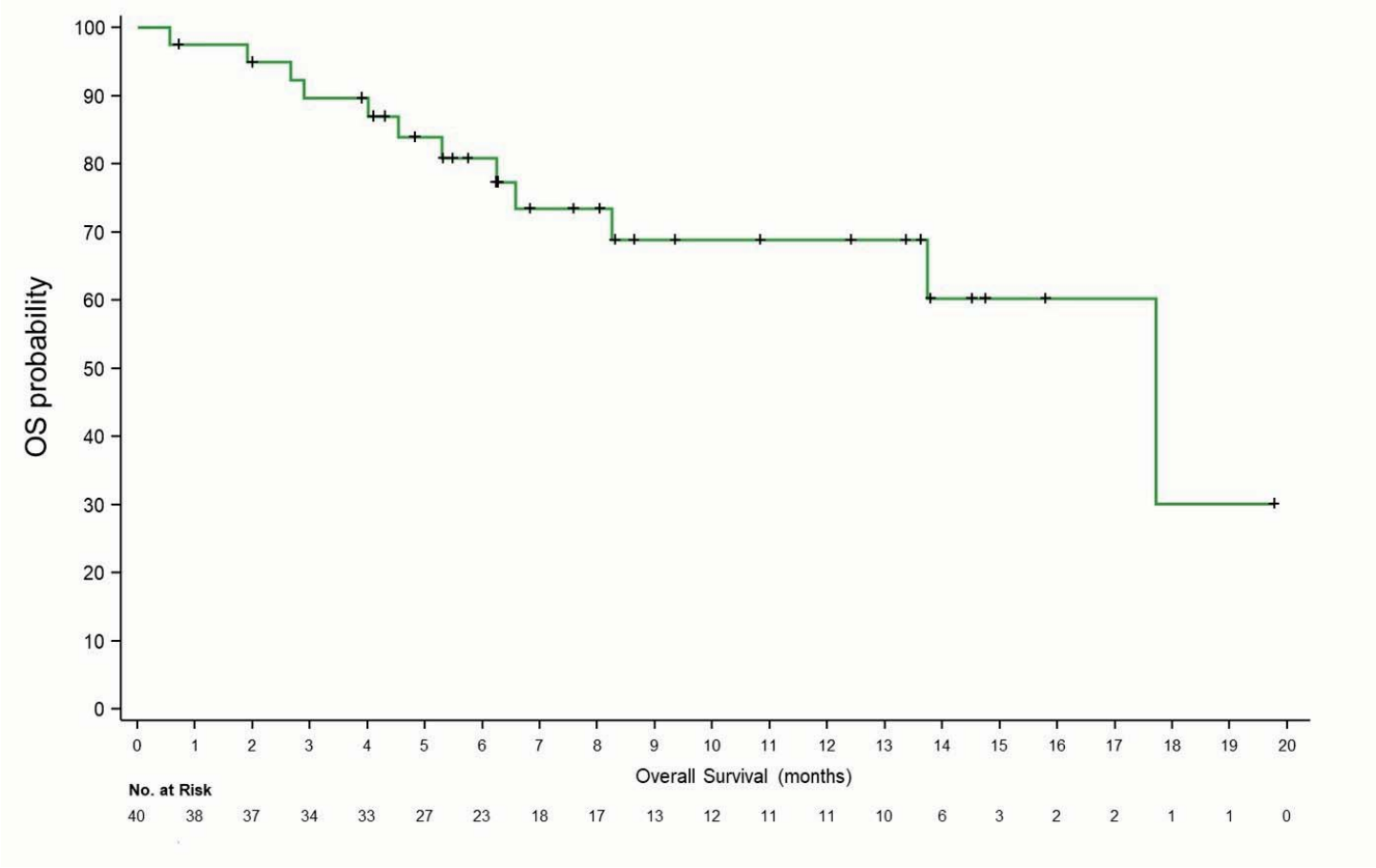
Data Cutoff Date of September 30, 2024

Population includes patients with RAS G12X mutant NSCLC who have received 1 or 2 prior lines of therapy, which must include prior immunotherapy and platinum chemotherapy administered either concurrently or sequentially, and have not received docetaxel previously. Adjuvant therapy or multimodal therapy with curative intent is considered prior therapy if disease progression occurred or treatment completion was within 6 months of first dose of daraxonrasib.

Median follow-up is 10.8 months.

We also reported interim OS data as of the NSCLC Data Cutoff Date for NSCLC Efficacy-Evaluable Patients (Figure 6). As of the NSCLC Data Cutoff Date, the median OS for NSCLC Efficacy-Evaluable Patients was 17.7 months (95% CI: 13.7, NE).

Figure 6. RMC-6236-001: Interim OS in NSCLC Efficacy-Evaluable Patients



Data Cutoff Date of September 30, 2024

Population includes patients with RAS G12X mutant NSCLC who have received 1 or 2 prior lines of therapy, which must include prior immunotherapy and platinum chemotherapy administered either concurrently or sequentially, and have not received docetaxel previously. Adjuvant therapy or multimodal therapy with curative intent is considered prior therapy if disease progression occurred or treatment completion was within 6 months of first dose of daraxonrasib.

Median follow-up is 10.8 months.

We believe these preliminary data observations from the RMC-6236-001 study as of the NSCLC Data Cutoff Date for NSCLC Efficacy-Evaluable Patients support the initiation of RASolve 301, our global, randomized Phase 3 trial comparing daraxonrasib against docetaxel in patients with RAS-mutated NSCLC who have been treated with one or two prior lines of therapy, which must have included immunotherapy or platinum chemotherapy.

Other Daraxonrasib Monotherapy

At the AACR Annual Meeting 2024, we reported individual case studies from the RMC-6236-001 study that showed examples of objective responses to daraxonrasib in patients with tumor types beyond PDAC or NSCLC, specifically patients with melanoma and with CRC. We believe that these observations may support further development opportunities for daraxonrasib.

Daraxonrasib with Pembrolizumab Combination

On December 2, 2024, we reported that, based on the initial observations of 20 previously treated patients in our RMC-LUNG-101 Phase 1b clinical study, as of a data cutoff date of October 28, 2024, the combination of daraxonrasib at a dose level of 200 mg daily with pembrolizumab at the standard dose level of 200 mg once every three weeks was generally well tolerated. TRAEs of Grade 1 aspartate aminotransferase (AST) elevation were reported in two patients (10%) and a TRAE of Grade 2 AST elevation was reported in one patient (5%). A TRAE of Grade 1 alanine transaminase (ALT) elevation was reported in one patient (5%), and a TRAE of

Grade 3 ALT elevation was reported in one patient (5%). We believe these observations support continued evaluation of the combination of daraxonrasib with pembrolizumab in NSCLC patients in the 1L setting.

Daraxonrasib with Elironrasib Combination

On December 2, 2024, we reported clinical safety and tolerability data for the combination of daraxonrasib at dose levels ranging from 100 mg daily to 300 mg daily with elironrasib (RMC-6291), our RAS(ON) oral tri-complex G12C inhibitor, at dose levels of 100 mg and 200 mg twice daily, from our RMC-6291-101 Phase 1b clinical study, which we refer to as the RMC-6291-101 study, as of a data cutoff date of October 28, 2024 (the Daraxonrasib/Elironrasib Data Cutoff Date) in patients with advanced RAS G12C mutant solid tumors.

In the RMC-6291-101 study, a total of 74 patients were evaluated for safety and tolerability as of the Daraxonrasib/Elironrasib Data Cutoff Date (Table 3). The combination of daraxonrasib with elironrasib was generally well tolerated across all dose levels tested. One Grade 4 TRAE (hypokalemia), which led to dose interruption, was associated with Grade 3 diarrhea. No Grade 5 TRAEs were observed.

Table 3. RMC-6291-101: TRAEs and TRAEs leading to dose modifications in patients treated with the combination of daraxonrasib and elironrasib

	All Dose Levels (N=74)				
Maximum Severity of TRAEs	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Any Grade**
Any TRAE	14 (19%)	26 (35%)	16 (22%)	1 (1%)	57 (77%)
TRAEs occurring in≥10% of patients, n (%)					
Rash[1]	21 (28%)	23 (31%)	4 (5%)	0 (0%)	48 (65%)
Diarrhea	23 (31%)	10 (14%)	1 (1%)	0 (0%)	34 (46%)
Nausea	17 (23%)	7 (10%)	0 (0%)	0 (0%)	24 (32%)
Vomiting	18 (24%)	6 (8%)	0 (0%)	0 (0%)	24 (32%)
Mucositis/Stomatitis	8 (11%)	9 (12%)	1 (1%)	0 (0%)	18 (24%)
Fatigue	8 (11%)	2 (3%)	3 (4%)	0 (0%)	13 (18%)
Anemia	4 (5%)	4 (5%)	2 (3%)	0 (0%)	10 (14%)
ALT increased	3 (4%)	6 (8%)	0 (0%)	0 (0%)	9 (12%)
AST increased	4 (5%)	3 (4%)	1 (1%)	0 (0%)	8 (11%)
Other select TRAEs, n (%)					
Electrocardiogram QT prolonged	0 (0%)	0 (0%)	2 (3%)	0 (0%)	2 (3%)
TRAEs leading to dose interruption of any study drug, n (%)	0 (0%)	12 (16%)	9 (12%)	1 (1%)	22 (30%)
TRAEs leading to dose reduction of any study drug, n (%)	1 (1%)	4 (5%)	2 (3%)	0 (0%)	7 (10%)
TRAEs leading to treatment discontinuation of any study drug, n (%)	0 (0%)	0 (0%)	2 (3%)	0 (0%)	2 (%)

Data Cutoff Date of October 28, 2024

Median duration of treatment was 2.3 months.

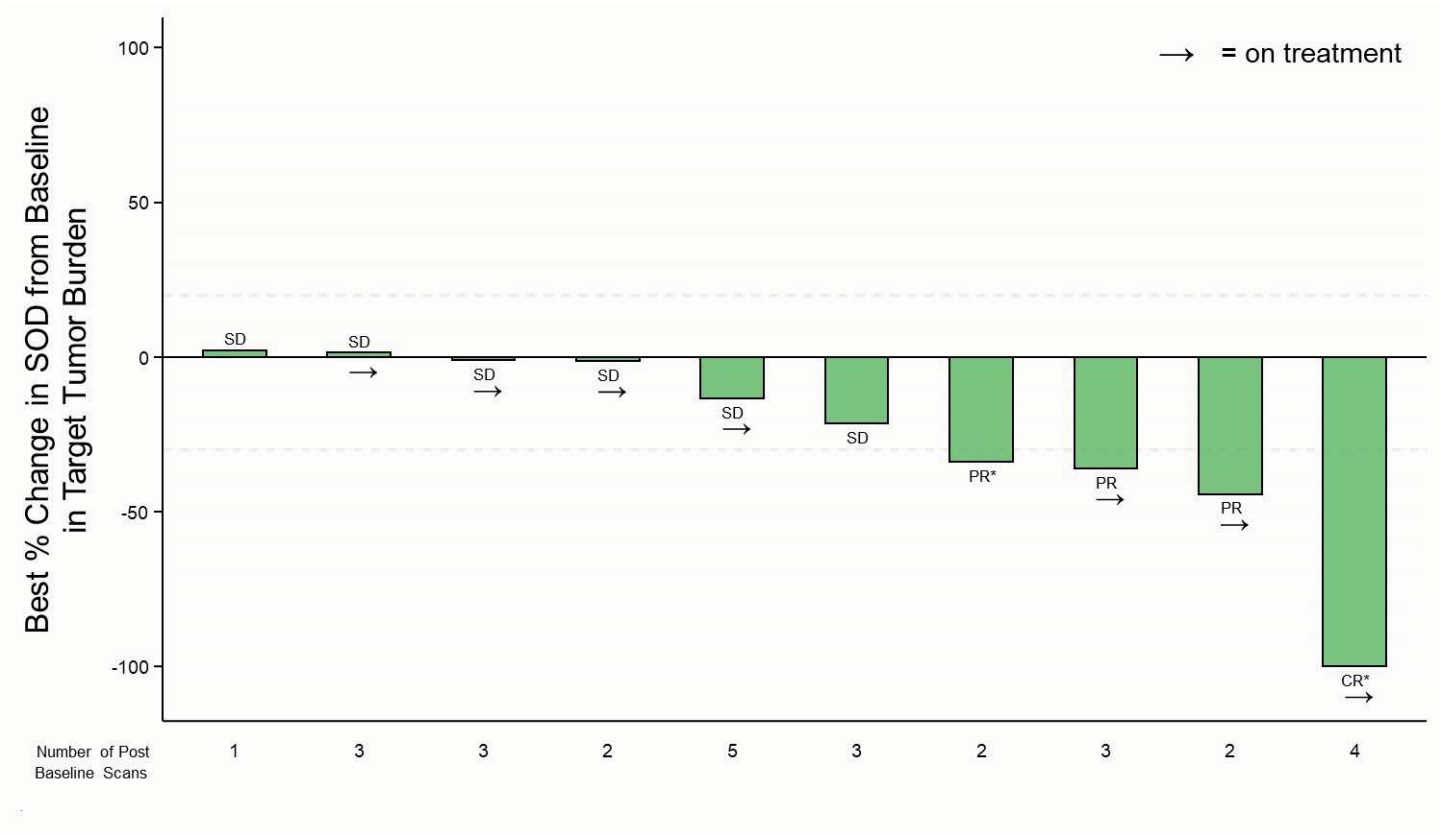
The mean dose intensities for elironrasib and daraxonrasib were 95% and 92%, respectively.

[1] Rash bundled term includes dermatitis acneiform, rash maculopapular, rash, rash pustular, and erythema.

ALT, alanine transaminase; AST, aspartate transferase.

We also reported best percentage change in tumor size from baseline for patients from the RMC-6291-101 study with CRC who were previously treated with a KRAS(OFF) G12C inhibitor as of the Daraxonrasib/Elironrasib Data Cutoff Date (Figure 7). The ORR for patients who received the first dose of study drugs at least 8 weeks prior to the Daraxonrasib/Elironrasib Data Cutoff Date was 25% (3 of 12 patients), including one patient with an unconfirmed complete response, and the disease control rate (DCR) was 92% (11 of 12 patients). As reference values, we also reported that the ORR for patients with CRC treated with daraxonrasib monotherapy at a dose of 300 mg daily in the RMC-6236-001 study as of a data cutoff date of September 30, 2024 was 9% (2 of 22 patients), and the ORR for patients with CRC previously treated with a KRAS(OFF) G12C inhibitor who were subsequently treated with elironrasib monotherapy at a dose of 200 mg twice daily in the RMC-6291-001 study as of a data cutoff date of October 28, 2024 was 0% (0 of 6 patients).

Figure 7. RMC-6291-101: Best percentage change in tumor size from baseline in patients with CRC who were previously treated with a KRAS(OFF) G12C inhibitor



Data Cutoff Date of October 28, 2024

ORR and DCR (CR+PR+SD) analyses include all patients who received first dose of study drug(s) at least 8 weeks prior to the data cutoff date (to allow 1 potential scan). Unconfirmed PRs (PR*) with treatment discontinued (will never confirm) were not considered responders but included in the denominator; ORR (by RECIST v1.1) included confirmed CRs/PRs and unconfirmed CRs/PRs who were still on treatment and may yet be confirmed. Two patients with 8 weeks follow up do not appear in waterfall due to one patient with no tumor assessment entered in database and one patient with missing target lesion measurements (overall response entered as SD). One patient with CR* has confirmed PR.

SOD, sum of diameters; SD, stable disease; CR, complete response; CR*, unconfirmed complete response; PR, partial response; PR*, unconfirmed PR; RECIST, Response Evaluation Criteria in Solid Tumors.

We believe these preliminary clinical safety and antitumor activity data provide initial proof-of-mechanism for a RAS(ON) Inhibitor doublet in patients previously treated with a KRAS(OFF) G12C inhibitor CRC patients and that they support continued development of our RAS(ON) Inhibitor doublets in a broad range of tumor types and earlier lines of therapy.

Elironrasib (RMC-6291)

Elironrasib (RMC-6291) is designed as a RAS(ON) oral G12C-selective inhibitor. It is designed to exhibit subnanomolar potency for suppressing RAS pathway signaling and growth of RAS G12C-bearing cancer cells and is engineered to be highly selective for RAS G12C over wild-type RAS and other cellular targets. Elironrasib is designed to be differentiated from first-generation KRAS(OFF) G12C inhibitors, which sequester the KRAS(OFF) G12C form, by its potential mechanism of directly inhibiting the RAS(ON) G12C form. We believe direct inhibition of the ON form offers important biological advantages, including more rapid termination of RAS signaling and more robust inhibition in the face of known resistance mechanisms.

Elironrasib Monotherapy

A monotherapy dose-escalation Phase 1b study of elironrasib, which we refer to as the RMC 6291-001 study, is ongoing.

On October 13, 2023, we reported interim preliminary safety and anti-tumor data from the RMC-6291-001 study as of an October 5, 2023 data cut-off date. The data demonstrated that elironrasib was generally well tolerated across dose levels. These data also

demonstrated preliminary evidence of clinical activity in patients with KRAS G12C NSCLC previously treated with, or naïve to, a KRAS(OFF) G12C inhibitor and preliminary evidence of clinical activity in patients with KRAS G12C CRC who had not been previously treated with a KRAS(OFF) G12C inhibitor. We observed that elironrasib was orally bioavailable and demonstrated dose-dependent pharmacokinetics and that reduction in ctDNA of the KRAS G12C allele across doses was correlated with clinical activity. We believe these data provided preliminary evidence of clinically meaningful differentiation of elironrasib from KRAS(OFF) G12C inhibitors.

Daraxonrasib with Elironrasib Combination

See "*Daraxonrasib (RMC-6236) – Daraxonrasib with Elironrasib Combination"* above.

Elironrasib with Pembrolizumab Combination

On December 2, 2024, based on the initial observations of 15 patients in our RMC-LUNG-101 Phase 1b clinical study, as of a data cutoff date of October 28, 2024, we reported that the combination of elironrasib at a dose level of 200 mg twice daily with pembrolizumab at the standard dose level of 200 mg once every three weeks was generally well tolerated. A TRAE of Grade 1 AST elevation was reported in one patient (7%) and a TRAE of Grade 1 ALT elevation was reported in one patient (7%). There were no TRAEs of Grade 2 or higher AST or ALT elevations reported. We believe these observations, together with its observations reported above from the combination of daraxonrasib with elironrasib and the combination of daraxonrasib with pembrolizumab, support exploration of the triplet combination of elironrasib, daraxonrasib, and pembrolizumab, which we believe has the potential to provide a chemotherapy-sparing option for patients with NSCLC in the 1L setting.

Zoldonrasib (RMC-9805)

Zoldonrasib (RMC-9805) is designed as a RAS(ON) oral G12D-selective inhibitor. It is designed to exhibit low nanomolar potency for suppressing RAS pathway signaling and growth of RAS G12D-bearing cancer cells and is engineered to covalently inactivate RAS G12D for irreversible inhibition. To our knowledge, zoldonrasib is the first drug candidate that covalently modified an aspartic acid residue in preclinical studies.

The RMC-9805-001 study, a monotherapy dose-escalation Phase 1/1b trial of RMC-9805, is ongoing. We have identified 1,200 mg once daily as the recommended zoldonrasib Phase 2 dose for PDAC.

Zoldonrasib Monotherapy

On October 25, 2024, we reported preliminary clinical safety, tolerability and activity data for zoldonrasib from the RMC-9805-001 study as of a data cutoff date of September 2, 2024 (the Zoldonrasib Data Cutoff Date) in patients with previously treated solid tumors harboring KRAS G12D mutations.

In the RMC-9805-001 study, a total of 179 patients treated across dose cohorts ranging from 150 mg to 1,200 mg once daily and from 300 mg to 600 mg twice daily were evaluated for safety and tolerability as of the Zoldonrasib Data Cutoff Date (Table 4). As of the Zoldonrasib Data Cutoff Date, the most common TRAEs that were observed were GI-related toxicities. TRAEs of any grade led to dose reduction in approximately 3% of patients. No TRAEs led to treatment discontinuation, and there were no treatment-related Grade 4 or 5 adverse events (AEs) or serious adverse events (SAEs) reported.

Table 4. RMC-9805-001: TRAEs for all patients treated with zoldonrasib (150 mg to 1,200 mg once daily or 300 mg to 600 mg twice daily)

	Total (n=179)			
Maximum Severity of TRAEs	**Grade 1**	**Grade 2**	**Grade 3**	**Any Grade**
TRAEs occurring in≥10% of patients, n (%)				
Nausea	48 (27%)	5 (3%)	0 (0%)	53 (30%)
Diarrhea	24 (13%)	5 (3%)	0 (0%)	29 (16%)
Vomiting	20 (11%)	6 (3%)	0 (0%)	26 (15%)
Other select TRAEs, n (%)				
ALT elevation	12 (7%)	0 (0%)	1 (1%)	13 (7%)
AST elevation	10 (6%)	1 (1%)	0 (0%)	11 (6%)
Rash‡	11 (6%)	0 (0%)	0 (0%)	11 (6%)
TRAEs leading to dose reduction, n (%)	5 (3%)	0 (0%)	0 (0%)	5 (3%)
TRAEs leading to treatment discontinuation, n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Median time on treatment was 2.8 months (range: 0.1 – 8.9 months).

‡ Includes preferred terms of dermatitis, dermatitis acneiform, dermatitis psoriasiform, eczema, erthyema, rash, rash erythematous, rash macular, rash maculo-papular, rash papular, rash pruritic and rash pustular.

ALT, alanine transaminase; AST, aspartate transferase.

We also reported the TRAEs for 99 patients who received 1,200 mg of zoldonrasib per day (1,200 mg once daily (n=60) or 600 mg twice daily (n=39)) as of the Zoldonrasib Data Cutoff Date (Table 5). The most common TRAEs observed were GI-related toxicities and rash. TRAEs of any grade led to dose reduction in approximately 4% of these patients. No TRAEs led to treatment discontinuation in these patients, and there were no treatment-related Grade 4 or 5 AEs or SAEs reported.

Table 5. RMC-9805-001: TRAEs for patients treated with 1,200 mg per day (1,200 mg once daily (n=60) or 600 mg twice daily (n=39))

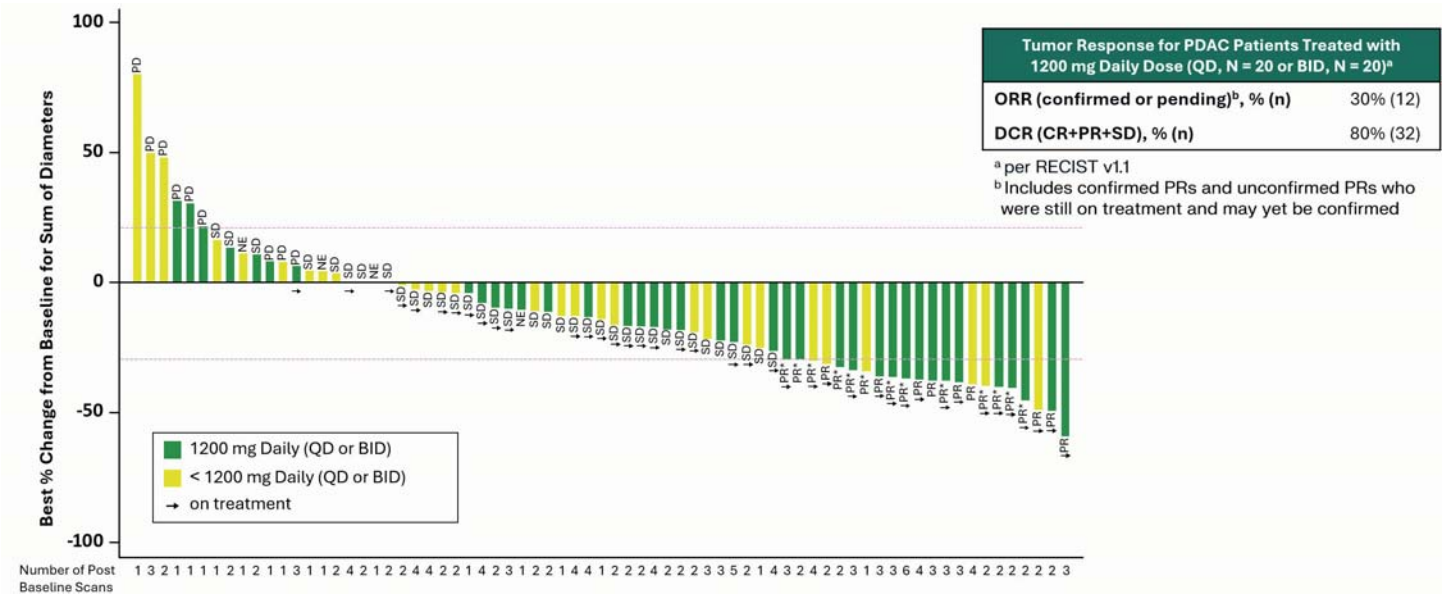
Maximum Severity of TRAEs	**Grade 1**	**Grade 2**	**Grade 3**	**Any Grade**
TRAEs occurring in≥10% of patients, n (%)				
Nausea	23 (23%)	4 (4%)	0 (0%)	27 (27%)
Diarrhea	16 (16%)	4 (4%)	0 (0%)	20 (20%)
Vomiting	13 (13%)	2 (2%)	0 (0%)	15 (15%)
Rash‡	10 (10%)	0 (0%)	0 (0%)	10 (10%)
Other select TRAEs, n (%)				
ALT elevation	5 (5%)	0 (0%)	1 (1%)	6 (6%)
AST elevation	3 (3%)	1 (1%)	0 (0%)	4 (4%)
Stomatitis	0 (0%)	0 (0%)	0 (0%)	0 (0%)
TRAEs leading to dose reduction, n (%)	4 (4%)	0 (0%)	0 (0%)	4 (4%)
TRAEs leading to treatment discontinuation, n (%)	0	0 (0%)	0 (0%)	0 (0%)

‡ Includes preferred terms of dermatitis, dermatitis acneiform, dermatitis psoriasiform, eczema, erthyema, rash, rash erythematous, rash macular, rash maculo-papular, rash papular, rash pruritic and rash pustular.

ALT, alanine transaminase; AST, aspartate transferase.

We also reported best percentage change in tumor size from baseline as of the Zoldonrasib Data Cutoff Date for patients with PDAC in the second-line or later (2L+) setting who received 1,200 mg per day (1,200 mg once daily (n=20) or 600 mg twice daily (n=20)) (Figure 8). For these patients who received a first dose of zoldonrasib at least 14 weeks prior to the Zoldonrasib Data Cutoff Date, the ORR (including both confirmed and pending responses) was 30%, and the DCR was 80%.)

Figure 8. RMC-9805-001: Best percentage change in tumor size from baseline and response rates for 2L+ PDAC patients treated with 1,200 mg daily



Data Cutoff Date of September 2, 2024

All treated patients with PDAC who received a first daily dose at least 14 weeks prior to the Zoldonrasib Data Cutoff Date (applies to Waterfall plot and ORR table); 3 additional patients (n=2 at 1,200 mg daily; n=1 at < 1,200 mg daily) are not displayed on the Waterfall plot due to withdrawal of consent or clinical progression.

Among patients with a response (confirmed or unconfirmed), 55% of first response occurred after 2 months of zoldonrasib treatment (all dose levels).

CR, complete response; NE, not evaluable; PD, progressive disease; PR, partial response; PRu*, unconfirmed partial response; SD, stable disease; RECIST, Response Evaluation Criteria in Solid Tumors.

We believe that these preliminary safety and clinical activity data as of the Zoldonrasib Data Cutoff Date support ongoing development of zoldonrasib as a single agent and in combination with other therapies, including daraxonrasib.

Commercial Plan

We intend to retain significant development and commercialization rights to our product candidates and, if marketing approval is obtained, to commercialize our product candidates on our own, or potentially with one or more collaborators, in the United States and other regions. We currently have limited sales, marketing and commercial product distribution capabilities. We have begun to build the necessary capabilities in the United States in support of a potential commercial launch, and over time expect to expand the infrastructure and capabilities for the United States, and potentially other regions, in connection with the advancement of our pipeline of product candidates. Clinical data, the indications and lines of therapy we pursue, the specific compounds from our pipeline we advance, our combination therapy and testing strategies, the size of the addressable patient populations, the commercial infrastructure and manufacturing needs and other factors, may all influence or alter our commercialization plans.

Manufacturing

We rely on and will continue to rely on contract manufacturing organizations (CMOs) for both drug substance and drug product. Currently, all of our manufacturing is outsourced to well-established third-party manufacturers. We have entered into contracts with CMOs for production of drug substance and drug product for our clinical trials and IND-enabling development studies, and plan to enter into additional contracts with these or other manufacturers for additional supply.

Our outsourced approach to manufacturing relies on CMOs to first develop manufacturing processes that are compliant with current Good Manufacturing Practice (cGMP), then produce material for preclinical and clinical studies. Our agreements with CMOs may obligate them to develop and qualify upstream and downstream processes, develop drug product process, validate (and, in some cases, develop) suitable analytical methods for test and release as well as stability testing, produce drug substance for preclinical testing, produce cGMP-compliant drug substance, or produce cGMP-compliant drug product. We conduct audits of CMOs prior to initiation

of activities under these agreements and monitor operations to ensure compliance with the mutually agreed process descriptions and to cGMP regulations.

Competition

The biotechnology and pharmaceutical industries, and the oncology sector in particular, are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property rights. While we believe that our discovery programs, technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, government agencies and public and private research institutions, among others.

Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products and the ease of use and effectiveness of any complementary diagnostics and/or companion diagnostics.

There are a number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. These treatments consist of small molecule drug products, biologics, cell-based therapies and traditional chemotherapy. Smaller and other early-stage companies may also prove to be significant competitors. In addition, academic research departments and public and private research institutions may be conducting research on compounds that could prove to be competitive.

There are several programs in clinical development targeting KRAS G12C, including programs directed at KRAS(OFF) G12C being conducted by Amgen Inc., Betta Pharmaceuticals Co., Ltd., Bristol Myers Squibb Company, Chengdu Huajian Future Technology Co. Ltd., D3 BIO, Inc., Eli Lilly, GenEros Biopharma Ltd., Genhouse Bio Co. Ltd., Guangzhou BeBetter Medicine Technology Co., Ltd., HUYA Bioscience, Innovent Biologics, Inc. (licensed to Genfleet Therapeutics), InventisBio, Jacobio Pharmaceuticals Co. Ltd., Jiangsu Hansoh Pharmaceutical Group Co., Ltd., Merck, Sharpe & Dohme LLC, Roche, Shanghai Junshi Biosciences Co., Ltd., Shanghai YingLi Pharmaceutical, Shouyao Holdings (Beijing) Co. Ltd. and Suzhou Zelgen Biopharmaceuticals. BridgeBio Pharma, Inc. and Frontier Medicines each have a dual KRAS(ON/OFF) G12C program in the clinic. There are also several clinical programs directed at KRAS G12D, including those being conducted by Astellas Pharma Inc., AstraZeneca, Eli Lilly, Genentech, Incyte Corporation, Jiangsu Hengrui Pharmaceuticals Company Ltd, Quanta Therapeutics, Tyligand Bioscience and Zelgen Biopharmaceuticals. In addition, there are a few clinical programs directed at KRAS G12V, including those being conducted by Affini-T Therapeutics and Yingkai Saiwei (Beijing) Biotechnology. Other clinical programs directed at mutant RAS, including pan-RAS inhibitors and Plk1 inhibitors, are being conducted, including those by Alaunos Therapeutics, Inc., BeiGene, Boehringer Ingelheim, Cardiff Oncology, Chugai Pharmaceutical Co., Ltd., Eli Lilly, Elicio Therapeutics, Gritstone bio, Inc., Moderna, Inc., Pfizer, Inc., Quanta Therapeutics, RasCal Therapeutics, Shanghai YingLi Pharmaceutical, Silenseed Ltd., Silexion Therapeutics and Targovax ASA.

The above list includes corporate competitors that we are currently aware of and that are currently conducting clinical trials or marketing in geographies where we currently anticipate conducting clinical trials for our product candidates. However, companies operating in other geographies and smaller and other early-stage companies may also prove to be significant competitors. In addition, academic research departments and public and private research institutions may be conducting research on compounds that could prove to be competitive.

The availability of coverage and reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. If and when our products receive FDA approval, they could be subject to maximum fair price (MFP) negotiation and application by the Centers for Medicare & Medicaid Services (CMS) under terms of the Inflation Reduction Act of 2022 (the IRA), nine years after launch in the United States. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter a given market.

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

Intellectual Property

Our success depends in part on our ability and the ability of our collaborators to obtain and maintain proprietary protection for our technology, programs and know-how related to our business, defend and enforce our intellectual property rights, in particular, our patent rights, preserve the confidentiality of our trade secrets, and operate without infringing valid and enforceable intellectual property rights of others. We endeavor to establish, maintain and enforce intellectual property rights that protect our business interests.

The term of individual patents depends upon the legal term of patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is generally 20 years from the earliest date of filing a non-provisional patent application, assuming the patent has not been terminally disclaimed over a commonly owned patent or a patent naming a common inventor, or over a patent not commonly owned but that was disqualified as prior art as the result of activities undertaken within the scope of a joint research agreement. In the United States, the term of a patent may also be eligible for patent term adjustment for delays within the U.S. Patent and Trademark Office (the USPTO). In addition, for patents that cover an FDA-approved drug, the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), may permit a patent term extension of up to five years beyond the expiration of the patent. While the length of such patent term extension is related to the length of time the drug is under regulatory review, patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per approved drug may be extended and only those claims covering the approved drug product, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek any available patent term extension to any issued patents we may be granted in any jurisdiction where such extensions are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and, if granted, the length of such extensions.

We also rely on trade secrets, know-how and confidential information relating to our programs to develop and maintain our proprietary position, and seek to protect and maintain the confidentiality of such items to protect aspects of our business that are not amenable to, or that we do not currently consider appropriate for, patent protection. Our trade secrets include, for example, certain program specific syntheses, manufacturing schema, formulations, biomarkers, patient selection strategies and certain aspects of our proprietary tri-complex technology platform. It is our policy to require our employees, consultants, contractors, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements prior to the commencement of employment or consulting relationships with us, and for employees, contractors and consultants to enter into invention assignment agreements with us. These agreements generally provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not to be disclosed to third parties except in specific circumstances. Where applicable, the agreements provide that all inventions to which the individual contributed as an inventor shall be assigned to us, and, as such, will become our property. There can be no assurance, however, that these agreements will be self-executing or otherwise provide meaningful protection or adequate remedies for our trade secrets or other proprietary information, including in the event of unauthorized use or disclosure of such information. We also seek to preserve the integrity and confidentiality of our trade secrets and confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in the measures we take to protect and preserve our trade secrets, such measures 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. For more information regarding the risks related to intellectual property, please see "Risk factors—Risks related to intellectual property."

Our Program-Specific Patent Portfolio

Our patent portfolio is directed to small molecules, platform methodologies and related technology. We seek patent protection for product candidates, development programs and related alternatives by filing and prosecuting patent applications in the United States and other countries, as appropriate.

We own and, in some cases, co-own or exclusively license, patents and patent applications related to our RAS tri-complex inhibitors and related platform technology. Our patent portfolio related to this program consists of ownership rights to several patent families that include filings covering compositions of matter or methods of using our development candidates alone or in combination with certain other therapeutic agents, or aspects pertaining to our tri-complex approach to RAS inhibition. The issued patents, and any patents issuing from these patent applications are expected to expire between 2031 (for patents originating from the Warp Drive Bio portfolio) and 2044 (for patents from our portfolio that did not originate from Warp Drive Bio), without accounting for potentially available patent term adjustments or extensions.

We also own, co-own or exclusively license patents and patent applications related to our RAS companion inhibitors. These patents include filings relating to compositions of matter or methods of using our development candidate. The issued patents, and any patents

issuing from these patent applications, are expected to expire between 2035 and 2043, without accounting for potentially available patent term adjustments or extensions.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, marketing and promotion, distribution, post-approval monitoring and reporting, sampling, and import and export of products, such as those we are developing. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Drug Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the FDCA) and its implementing regulations. FDA approval is required before any new drug can be marketed in the United States. Drugs are also subject to other federal, state and local statutes and regulations. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA clinical holds, refusal to approve pending applications, withdrawal of an approval, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of certain extensive preclinical laboratory tests and animal studies, including safety and toxicity studies performed in accordance with applicable regulations, including the FDA's Good Laboratory Practice (GLP) regulations;
- manufacture of clinical drug supply in accordance with the FDA's cGMP regulations for use in clinical studies;
- submission to the FDA of an Investigational New Drug application (IND), which must become effective before human clinical studies may begin and must be updated annually or when certain changes or updates are made;
- approval by an independent institutional review board (IRB) or ethics committee representing each clinical site before a clinical study may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice (GCP), regulations to establish the safety and efficacy of the product candidate for each proposed indication;
- preparation of and submission to the FDA of a New Drug Application (NDA) after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility(ies) where the product is manufactured to assess compliance with cGMP regulations, and of potential inspection selected clinical investigation sites to assess compliance with GCP;
- payment of user fees for FDA review of the NDA; and
- FDA review and approval of an NDA to permit commercial marketing of the product for its particular labeled uses in the United States.

Preclinical and Clinical Studies

Preclinical tests include laboratory (in vitro) evaluation of product chemistry, formulation and toxicity, as well as animal (in vivo) studies to assess the characteristics and potential safety and efficacy of the product candidate. The conduct of certain preclinical tests that provide safety and toxicological information must comply with certain federal regulations and requirements, including GLP. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about the product's chemistry, manufacturing and controls (CMC) and any available human data or literature to support use of the product in humans. An IND is a request for allowance from the FDA to administer an investigational product to humans. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical studies. In such a case, the IND

may be placed on clinical hold, and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical studies can begin.

For each successive clinical trial conducted with the investigational drug, a separate, new protocol submission to an existing IND must be made, along with any subsequent changes to the investigational plan. Sponsors are also subject to ongoing reporting requirements, including submission of IND safety reports for any serious adverse experiences associated with use of the investigational drug or findings from preclinical studies suggesting a significant risk for human subjects, as well as IND annual reports on the progress of the investigations conducted under the IND.

Clinical studies involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with GCP, which include among other things, the requirement that all research subjects provide their informed consent for participation in each clinical study. Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical study site's IRB before a study may be initiated at the site, and the IRB must monitor the study until completed. Sponsors of clinical trials generally must register and report ongoing clinical studies and clinical study results to public registries, including the website maintained by the U.S. National Institutes of Health, ClinicalTrials.gov.

Human clinical trials are typically divided into three or four phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase 1. The drug is initially introduced into healthy human subjects or into patients with the target disease or condition. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The drug is administered to a limited patient population to evaluate tolerance and optimal dose, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy. Multiple Phase 2 trials may be conducted to obtain additional data prior to beginning Phase 3 trials.
- Phase 3. The drug is administered to an expanded patient population, generally at geographically dispersed clinical study sites to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational product and to provide an adequate basis for product labeling.

In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical studies after approval. In other cases, a sponsor may voluntarily conduct additional clinical studies after approval to gain more information about the drug in the approved indication. Such post-approval studies are sometimes referred to as Phase 4 clinical studies.

The FDA, the IRB, other regulatory authorities or the clinical study sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. The sponsor may also suspend or terminate a clinical study based on evolving business objectives and/or competitive climate.

Concurrent with clinical trials, companies may complete additional in vivo studies and develop additional information about the characteristics of the product candidate. Companies must also finalize a process for manufacturing the product in commercially applicable quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, must use validated methods for testing the product against specifications to confirm its identity, strength, quality and purity. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of preclinical studies and other non-clinical studies and clinical trials, together with detailed information relating to the product's CMC and proposed labeling, among other things, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The submission of an NDA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

An NDA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, among other things. Data can come from company-sponsored clinical studies intended to test the

safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational product to the satisfaction of the FDA.

The FDA reviews all submitted NDAs before it accepts them for filing. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing 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 application for filing. In this event, the application must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under applicable performance goals established by the Prescription Drug User Fee Act (the PDUFA), the FDA endeavors to review applications subject to standard review within ten to twelve months, and to review applications subject to priority review within six to eight months, depending on whether the drug is a new molecular entity.

The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, the FDA may inspect one or more clinical sites to assure that relevant study data were obtained in compliance with GCP requirements.

After the FDA evaluates the NDA and conducts any inspections of manufacturing facilities and/or clinical trial sites, it may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information, including additional clinical trials or other significant and time-consuming requirements related to clinical trials, nonclinical testing or manufacturing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, as a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy (REMS) program to help ensure that the benefits of the drug outweigh its risks. If the FDA determines a REMS program is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS program may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, or other elements to assure safe use, such as limitations on who may prescribe or dispense the drug, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, all REMS programs must include a timetable to periodically assess the strategy following implementation. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications.

Further, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety and efficacy, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Moreover, changes to the conditions established in an approved application, including changes in indications, labeling or manufacturing processes or facilities may require submission and FDA approval of a new NDA or a supplemental NDA (sNDA) before the changes can be implemented. An sNDA for a new indication typically requires clinical data similar to that supporting the original approval, and the FDA uses similar procedures in reviewing supplements as it does in reviewing original applications.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates, and we may seek one or more of these programs for our current or future products.

Investigational drug products may be 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. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for frequent interactions with the FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. A fast track product candidate may also be eligible for rolling review,

where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product 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 FDA's commitment to expedite the development and review of the product, including involvement of senior managers.

After an NDA is submitted for a product candidate, including a product candidate with a fast track designation and/or breakthrough therapy designation, the NDA may be eligible for priority review. An NDA is eligible for priority review if the product candidate has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. Depending on whether a drug contains a new molecular entity, priority review designation means the FDA's goal is to take an action on the marketing application within six months of the 60-day filing date, compared with 12 months under standard review.

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product 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 accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled confirmatory clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit, and may require that such confirmatory trials are underway prior to granting any accelerated approval. The FDA may withdraw approval of a drug or an indication approved under accelerated approval if, for example, sponsor fails to conduct the confirmatory trial in a timely manner, or if the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

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

Orphan Drug Designation

We intend to pursue orphan drug designation for one or more of our product candidates with respect to certain oncology indications, as appropriate, with the potential to obtain orphan drug exclusivity for our products, if approved.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

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 drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Orphan drug exclusivity also could block the approval of a product for seven years if a competitor obtains approval of the "same drug" as defined by the FDA, or if a product candidate is determined to be contained within the approved product for the same disease or condition. Among the other benefits of orphan drug designation are opportunities for grant funding towards clinical trial costs, tax credits for certain research and a waiver of the application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the disease or condition for which it received orphan designation. In addition, 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.

Pediatric Information and Pediatric Exclusivity

Under the Pediatric Research Equity Act (PREA), certain NDAs and certain sNDAs must contain data to assess the safety and efficacy 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 product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. 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. Generally, the FDA requires that a sponsor that is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (iPSP), within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of a Phase 2/3 or Phase 3 study. The iPSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the iPSP. A sponsor can submit amendments to an agreed-upon iPSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

A drug product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug listing and registration, recordkeeping, periodic reporting, product sampling and distribution, adverse event reporting and advertising, marketing and promotion. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. While physicians may prescribe a product for uses in patient populations that are not described in the product's approved labeling, or "off-label" uses, manufacturers may only promote a product for the approved indications and in accordance with the provisions of the approved labeling of such product. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of "off-label" uses, and a company that is found to have improperly promoted "off-label" uses may be subject to significant liability.

After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved NDA. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMP after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced and announced inspections by the FDA and these state agencies, during which the applicable agency inspects manufacturing facilities to assess compliance with cGMP requirements and other laws. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon manufacturers and their subcontractors. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. The FDA may withdraw approval of a product if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of 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 a product, complete withdrawal of the product from the market or product recalls;
- fines, warning or untitled letters or holds on clinical studies;

- refusal by the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal by the FDA to permit the import or export of products;
- mandated modifications of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

Manufacturers also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for "off-label" use, industry-sponsored scientific and educational activities and promotional activities involving the internet.

The FDA may also require post-approval studies and clinical trials if the FDA finds that scientific data, including information regarding related drugs, deem them appropriate. The purpose of such studies can include, among other things, assessments designed to evaluate a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

International Regulation

In addition to regulations in the United States, we could become subject to a variety of foreign regulations regarding development, approval, commercial sales and distribution of our products if we seek to market our product candidates in other jurisdictions. Regardless of whether we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-Clinical Studies and Clinical Trials

Similar to the United States, the various phases of non-clinical and clinical research in the European Union, or EU, are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of GLP as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organisation for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), GCP guidelines, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and, in most EU member states, the sponsor is liable to provide "no fault" compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation (CTR), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022, with a three-year transition period. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

The CTR provides for a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with cGMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In order to market our product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization (MA). To obtain regulatory approval of a product candidate under EU regulatory systems, we must submit a MA application (MAA). The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs.

- "Centralized MAs" are issued by the European Commission through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency (EMA), and are valid throughout the EU. The centralized procedure is compulsory for certain types of medicinal products such as (i) medicinal products derived from biotechnological processes, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products (ATMPs) (such as gene therapy, somatic cell therapy and tissue engineered products) and (iv) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as cancer, HIV/AIDS, diabetes, neurodegenerative diseases or autoimmune diseases and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Once the evaluation is finalized, the EMA sends the CHMP's opinion to the European Commission which has up to 67 days to adopt a legally binding decision and issue a MA.
- "National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure described above. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state 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. The timeframe to obtain national MAs varies depending on the concerned procedure. Under the mutual recognition procedure, the reference member state (where the medicinal product is already authorized) must prepare the assessment report within 90 days. The concerned member states have up to 90 days to recognize the decision of the reference member state, and approve the summary of product characteristics, labeling and packaging. Then, each member state has a 30-day period to grant the national MA. Under the decentralized procedure, the evaluation period is 120 days for the reference member state, followed by a 90-day period for the concerned member states to approve the summary of product characteristics, labeling and packaging. Then, each member state has a 30-day period to grant the national MA. In order to grant the MA, the EMA or the competent authorities of the EU member states make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance.

Data and Marketing Exclusivity

In the EU, new products authorized for marketing (i.e., reference products) generally receive eight years of data exclusivity and an additional two years of market exclusivity upon receipt of MA. If granted, the data exclusivity period prevents generic and biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar 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 or biosimilar 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 11 years if, during the first 8 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 or biological entity, and products may not qualify for data exclusivity.

Orphan Medicinal Products

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition; (2) either (a) such condition affects not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from the orphan status, would not generate sufficient return in the EU to justify the necessary investment for its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized for marketing in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition. In the EU, orphan designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Orphan designation must be requested before submitting an MAA. An EU orphan designation entitles a party to incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized procedure. Upon grant of a MA, orphan medicinal products are entitled to ten years of market exclusivity for the approved indication, which means that the competent authorities cannot accept another MAA, or grant a MA, or accept an application to extend a MA for a similar medicinal product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan (PIP). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The orphan exclusivity period may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan destination, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, MA may be granted to a similar product for the same indication at any time if: (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

The aforementioned EU rules are generally applicable in the European Economic Area (EEA), which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Brexit and the Regulatory Framework in the United Kingdom

Since the end of the Brexit transition period on January 1, 2021, and the implementation of the Windsor Framework on January 1, 2025, the United Kingdom (UK) has not been directly subject to EU laws with respect to medicinal products. The EU laws that have been transposed into UK law through secondary legislation remain applicable in Great Britain (GB) (comprising England, Scotland and Wales), but new legislation such as the (EU) CTR is not applicable in GB.

Since January 1, 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) has been the UK's standalone medicines and medical devices regulator. As a result of the Northern Ireland Protocol, different rules applied in Northern Ireland than in GB; broadly, Northern Ireland continued to follow the EU regulatory regime. However, on January 1, 2025, a new arrangement called the "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes, and EU labelling and serialization requirements in relation to Northern Ireland, and introduces a UK-wide licensing process for medicinal products.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment and a rolling review procedure. In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain an MA to commercialize products in the UK. Since January 1, 2024, an international recognition procedure has been in place whereby the MHRA has been able to conduct targeted assessments of an MAA by recognizing approvals from trusted partner agencies such as the European Medicines Agency.

The UK regulatory framework in relation to clinical trials is derived from pre-existing EU legislation (as implemented into UK law, through secondary legislation). Whether the regulation of clinical trials in the UK will mirror the (EU) CTR in the long term is not yet certain; however, on December 12, 2024, the UK government introduced a legislative proposal - the Medicines for Human Use (Clinical Trials) Amendment Regulations 2024 - that, if implemented, will replace the current regulatory framework for clinical trials in the UK. The legislative proposal aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered. The UK government has provided the legislative proposal to the UK Parliament for its review and approval. Once the legislative proposal is approved (with or without amendment), which is expected to occur in early 2026, it will be adopted into UK law. Under the terms of the Northern Ireland Protocol, provisions of the (EU) CTR which relate to the manufacture and import of investigational medicinal products and auxiliary medicinal products currently apply in Northern Ireland.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal and state anti-kickback, fraud and abuse, false claims, consumer fraud, pricing reporting, and transparency laws and regulations, as well as similar laws in jurisdictions outside the United States.

For example, the U.S. federal Anti-Kickback Statute prohibits, among other things, individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.

The federal civil and criminal false claims laws, including the civil False Claims Act, prohibit, among other things, any individual or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim 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), created additional federal civil and criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation.

The federal Physician Payments Sunshine Act 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 specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (defined to include physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse midwives) and teaching hospitals, and further requires applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-government third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives.

Violation of any of such laws or any other government regulations that apply may result in penalties, including, without limitation, civil and criminal penalties, damages, fines, additional reporting obligations, the curtailment or restructuring of operations, exclusion from participation in government healthcare programs and individual imprisonment.

Data Privacy and Security

We may be subject to numerous federal, state and foreign laws, regulations that govern the collection, use, disclosure and protection of health-related and other personal information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts and can result in investigations, proceedings or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufacturers to provide scientific and clinical support for the use of a product to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In addition, third-party payors are increasingly reducing reimbursements for pharmaceutical products and services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product at all could reduce physician usage and patient demand for the product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability of manufacturers to sell products profitably.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the ACA), was signed into law, which substantially changed the way healthcare is financed by both government and private insurers in the United States. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers that sell certain "branded prescription drugs" to specified federal government programs; expanded eligibility criteria for Medicaid programs; created a 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 and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive and congressional challenges to certain aspects of the ACA. In June 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which will remain in effect through 2032, with the exception of a temporary suspension that occurred from May 1, 2020 through March 31, 2022, absent additional congressional action. Moreover, there has recently been heightened government scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. On August 16, 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023) and replaces the Part D coverage gap discount program with a new manufacturer discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price reporting and other transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. Furthermore, there has been increased interest by third-party payors and government authorities in reference pricing systems and publication of discounts and list prices.

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

Employees and Human Capital Resources

As of December 31, 2024, we had 534 full-time employees. Within our workforce, as of December 31, 2024, 423 employees were engaged in research and development. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include meeting hiring goals, deepening our oncology and public company expertise, integrating new employees, and retaining, incentivizing and developing our existing employees. We provide competitive compensation and benefit programs, including competitive salaries, incentive programs, equity awards, an employee stock purchase plan, healthcare and insurance benefits. The principal purposes of our equity incentive programs are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and to align the interests of these individuals with those of our stockholders. We regularly review our compensation practices to support our employees, including evaluating innovative health and wellness programs to continue to respond to employee needs.

We are committed to creating an environment where diverse perspectives are encouraged and supported. This commitment is memorialized as one of our corporate core values (Inclusiveness and Fairness) and is brought to life for every employee during our cultural integration sessions for new hires and through an informal network of cultural champions that we foster. As of December 31, 2024, females represented 58% of our full-time employees, and 426 of our employees self-identified their race, of which 55% self-identified as an “underrepresented minority,” as that term is defined by Nasdaq rules.

We are equally committed to the development of our employees and one of our corporate core values (Exceptional Together) captures this commitment. We offer our employees career-specific training and resources and support development opportunities through company-sponsored programs, including learning, mentoring, and coaching opportunities. We host regular company-wide sessions where our employees discuss ideas related to corporate initiatives and scientific breakthroughs and recognize each other’s contributions. In addition, we conduct an anonymous all-employee engagement survey at least annually, and take the results of this survey into account in management of our employees and business.

Corporate Information

We were founded in October 2014 as a Delaware corporation. Our principal executive offices are located at 700 Saginaw Drive, Redwood City, California 94063, and our telephone number is (650) 481-6801.

On November 9, 2023, we completed the announced acquisition of EQRx, Inc., a Delaware corporation (EQRx), pursuant to an Agreement and Plan of Merger, dated as of July 31, 2023. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Acquisition of EQRx, Inc".

Our website address is *www.revmed.com*. We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC in accordance with the Securities Exchange Act of 1934, as amended (the Exchange Act). These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document or any other document that we file with or furnish to the SEC. The SEC maintains a site on the worldwide web that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below or other risks we face could materially and adversely affect our business, competitive position, financial condition, results of operations, cash flows and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

Risks related to our limited operating history, financial position and need for additional capital

We are a clinical-stage precision oncology company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability, which, together with our limited operating history, makes it difficult to assess our future viability.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage precision oncology company, and we have only a limited operating history upon which you can evaluate our business and prospects. We currently have no products approved for commercial sale, have not generated any revenue from sales of products and have incurred losses in each year since our inception in October 2014. 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.

Since our inception, we have incurred significant net losses. Our net losses were $600.1 million, $436.4 million and $248.7 million, for the years ended December 31, 2024, 2023 and 2022, respectively. As of December 31, 2024, we had an accumulated deficit of $1.7 billion. We have funded our operations to date primarily with proceeds from the sale of common stock and preferred stock, as well as upfront payments and research and development cost reimbursement received under our collaboration agreement with Genzyme Corporation, an affiliate of Sanofi (the Sanofi Agreement). The Sanofi Agreement was terminated in June 2023, and Sanofi has no further reimbursement obligations following this termination. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring and discovering development programs, securing intellectual property rights and conducting discovery, research and development activities for our programs. We have not yet demonstrated our ability to successfully complete any clinical trials, including pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Our product candidates will require substantial additional development time and resources before we will be able to apply for or receive regulatory approvals and, if approved, begin generating revenue from product sales. We expect to continue to incur significant expenses and operating losses for the foreseeable future.

We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with our collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our development programs. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate future revenue from product sales depends heavily on our, and any potential future collaborators', success in:

- completing clinical and preclinical development of product candidates and programs and identifying and developing new product candidates;
- seeking and obtaining marketing approvals for our product candidates;
- launching and commercializing product candidates for which we obtain marketing approval by establishing a sales force, marketing, medical affairs and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- achieving adequate coverage and reimbursement by third-party payors for our product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for our product candidates, if approved;
- obtaining market acceptance of our product candidates as viable treatment options, if approved;

- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations under such collaborations;
- maintaining, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trademarks, trade secrets and know-how;
- defending against third-party interference, infringement or other intellectual property-related claims, if any; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate, including prior to a potential launch of any approved product candidate. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration (the FDA), the European Medicines Agency (the EMA) or other regulatory agencies to perform clinical trials or studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We will require substantial additional financing to achieve our goals, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Our operations have consumed substantial amounts of cash since our inception. Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our initial preclinical and clinical product candidates.

Preclinical studies, clinical trials and additional research and development activities will require substantial funds to complete. As of December 31, 2024, we had cash, cash equivalents and marketable securities of $2.3 billion. Through December 31, 2024, we have raised $2.1 billion in underwritten public offerings, net of underwriting discounts and commissions and offering expenses and have completed sales generating $246.4 million in gross proceeds pursuant to at-the-market equity offering programs. Our acquisition of EQRx, Inc. (the EQRx Acquisition) added $1.1 billion to our working capital in 2023. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our current and future programs and to prepare for their potential commercialization. If we are able to gain marketing approval for our product candidates, we will require significant additional amounts of cash in order to launch and commercialize our product candidates, if approved, to the extent that their launch and commercialization are not the responsibility of another collaborator that we may contract with in the future. In addition, other unanticipated costs may arise. Because the design and outcome of our current, planned and potential future clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

The timing and amount of our future funding requirements depends on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates and programs, and of conducting preclinical studies and clinical trials;
- the cost of manufacturing our current and future product candidates for clinical trials in preparation for marketing approval and in preparation for commercialization;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates if clinical trials are successful;
- the cost of commercialization activities for any of our product candidates, whether alone or in collaboration, including marketing, sales and distribution costs if any product candidate is approved for sale;
- our ability to establish and maintain strategic licenses 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 timing, receipt and amount of sales of, profit share or royalties on, our future products, if any;
- the emergence of competing cancer therapies or other adverse market developments; and
- any plans to acquire or in-license other programs or technologies.

We will require substantial additional financing for our development efforts for our current and future programs and to prepare for their potential commercialization. We do not have any committed external source of funds or other support for these activities, and we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, credit or loan facilities, acquisitions, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce the scope of or terminate one or more of our preclinical studies, clinical trials, or other research and development activities or eliminate one or more of our development programs altogether; or
- delay, limit, reduce the scope of or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize any future approved products, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

Our operating results may fluctuate significantly, which will make our future results difficult to predict and could cause our results to fall below expectations.

Our quarterly and annual operating results may fluctuate significantly, which will make it difficult for us to predict our future results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and commercialization activities, which may change from time to time;
- the timing and status of enrollment for our clinical trials;
- the timing of regulatory approvals, if any, in the United States and internationally;
- the timing of expanding our operational, financial and management systems and personnel, including personnel to support our clinical development, quality control, manufacturing and commercialization efforts and our operations as a public company;
- the cost of manufacturing, as well as building out our supply chain, which may vary depending on the quantity of productions, and the terms of any agreements we enter into with third-party suppliers;
- the timing and amount of any milestone, royalty or other payments due under any current or future collaboration or license agreements;
- coverage and reimbursement policies with respect to any future approved products, and potential future drugs that compete with our products;
- the timing and costs to establish sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with one or more collaborators;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- the level of demand for any future approved products, which may vary significantly over time;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or collaboration partners.

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 operating guidance we may provide.

Risks related to product development and regulatory process

Our business is dependent on the successful development of our current and future product candidates. If we, alone or in collaboration, are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any of our product candidates, or we experience significant delays in doing so, our business will be materially harmed.

Our business is dependent on the successful development of our current and future product candidates. We are evaluating certain of our product candidates in exploratory clinical trials, both as monotherapy and in combination regimens, and currently plan to conduct pivotal clinical trials for our RAS(ON) inhibitors, including the RASolute 302 study and the RASolve 301 study with daraxonrasib, both of which we recently initiated. The remainder of our programs are in the preclinical stage, and the clinical development of these programs is subject to our continuing assessment of our portfolio priorities. The success of our business, including our ability to finance our company and generate revenue from products in the future, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. Our current product candidates, and any of our future product candidates, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from product sales.

We have not previously submitted a New Drug Application (NDA) to the FDA or similar applications to a comparable foreign regulatory authority, for any product candidate. An NDA or other relevant regulatory application must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant application must also include significant information regarding the CMC for the product. We cannot be certain that our current or future product candidates will be successful in clinical trials or receive regulatory approval. Further, even if they are successful in clinical trials, our product candidates or any future product candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we or collaborators gain regulatory approval and have commercial rights, as well as the availability of competitive products, whether there is sufficient third-party reimbursement and adoption by physicians.

We plan to seek regulatory approval to commercialize our product candidates both in the United States and in select foreign countries, alone or in collaboration. While the scope of regulatory approval generally is similar in other countries, in order to obtain separate regulatory approval in other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of drugs, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions.

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

- successful completion of clinical trials and preclinical studies;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- allowance to proceed with clinical trials under Investigational New Drug applications (INDs) by the FDA or under comparable applications by comparable regulatory authorities for our planned clinical trials or future clinical trials;
- successful enrollment and completion of clinical trials, particularly where competitors may also be recruiting patients;
- data from our clinical programs that supports an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt and maintenance of marketing approvals from applicable regulatory authorities;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if one of our product candidates is approved;

- entry into collaborations to further the development of our product candidates;
- obtaining and maintaining our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- enforcing and defending intellectual property rights and claims;
- obtaining and maintaining regulatory exclusivity for our product candidates;
- successfully launching commercial sales of our product candidates, if approved;
- acceptance of the product candidate's benefits and uses, if approved, by patients, the medical community and third-party payors;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates prior to or following any approval;
- effectively competing with other therapies; and
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors.

If we or our collaborators are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our current or future product candidates, which would materially harm our business. If we or our collaborators do not receive marketing approvals for any of our product candidates, we may not be able to continue our operations.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which would have an adverse effect on our business.

In order to obtain approval from the FDA or comparable foreign authorities to market a new small molecule product, we must demonstrate proof of safety and efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical studies that support our planned INDs in the United States. We cannot be certain of the timely completion or outcome of our preclinical studies and cannot predict if the FDA or foreign authorities will accept our proposed clinical programs or if the outcome of our preclinical studies will ultimately support further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing additional clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting preclinical studies may cause us to incur additional operating expenses. Moreover, we may be affected by delays or decisions to discontinue development associated with the studies of certain programs that are the responsibility of our current or potential future collaborators over which we have no control. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other *in vivo* or *in vitro* data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design and obtaining regulatory allowance or authorization to commence clinical trials; and
- obtaining sufficient quantities of starting materials, intermediate materials and our product candidates for use in preclinical studies and clinical trials from third-party suppliers on a timely basis.

Moreover, even if clinical trials do begin for our preclinical programs, our development efforts may not be successful, and clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety or efficacy to obtain the requisite regulatory approvals for any of our product candidates. Even if we obtain positive results from preclinical studies or initial clinical trials, we may not achieve the same success in future trials.

Historically, direct inhibition of any RAS protein has been challenging due to a lack of tractable, or "druggable," binding pockets. Given this approach is unproven, it may not be successful.

Historically, direct inhibition of any RAS protein has been challenging due to a lack of tractable, or "druggable," binding pockets. Our tri-complex technology has enabled us to design potent, cell-active inhibitors of multiple mutant RAS(ON) proteins. We are not aware of any programs in clinical development that have successfully targeted any RAS(ON) protein. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies.

The results of preclinical studies and early-stage clinical trials may not be predictive of future results.

The results of preclinical studies may not be predictive of the results of clinical trials, and the results of early-stage clinical trials may not be predictive of the results of the later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. For example, historically, targeted therapies have been susceptible to resistance mutations in cancer cells that facilitate escape from anti-tumor response. Should such resistance mutations arise in patients being treated with our product candidates, the clinical benefit associated with those candidates may be compromised.

We recently initiated the RASolute 302 study and the RASolve 301 study with daraxonrasib, and are currently planning additional registrational clinical trials for RMC-6236 and our other RAS(ON) inhibitors. These studies may not produce results that are consistent with expectations or that are predicted by our earlier clinical observations for these compounds. Our plans for these and future planned registrational trials are, and will be based on our observations from the results of early-stage clinical trials using the same product candidates. Based on data from early-stage clinical trials, we will select, subject to regulatory feedback, the proposed indication, line of therapy, study design and dose and dose schedule for our registrational studies. However, these registrational studies, if initiated, may not be successful and may not produce results that are consistent with our expectations, based on our earlier clinical observations, including because other trial designs may have greater likelihood of development success.

There can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for product candidates proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. Even if clinical trials with our product candidates are completed, the results may not be sufficient to obtain regulatory approval of any products.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on the ability to enroll a sufficient number of patients who remain in the trial until its conclusion. 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 in these trials to such trial's conclusion as required by the FDA or other comparable regulatory authorities. We or our future collaborators may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- our ability to enroll a sufficient number of patients with mutations in the signaling pathways that our therapies are designed to target;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of our product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the ability to obtain and maintain patient consents for participation in our clinical trials and, where appropriate, biopsies for future patient enrichment efforts;
- the risk that patients enrolled in clinical trials will not remain on the trial through the completion of evaluation; and

- the ability of clinical trial investigators to enroll patients in cases of outbreak of disease, geopolitical or other conflicts or natural disasters, including as a result of the ongoing war between Russia and Ukraine or escalation of conflicts in the Middle East.

In addition, our clinical trials will compete with approved therapies, including sotorasib and adagrasib, as well as other clinical trials for product candidates that are in the same therapeutic areas (and that seek to evaluate patients with cancer cells having the same mutations), particularly for patients having KRAS G12C or KRAS G12D mutations, as our current and potential future product candidates. This competition and competition with approved therapies will reduce the number and types of patients available for clinical trials involving our product candidates, because some patients who might have opted to enroll in our trials may instead opt to pursue a treatment regimen using an approved therapy or enroll in a trial conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such sites. Moreover, because our current and potential future product candidates may represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in our ongoing or any future clinical trials.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

We and our collaborators are currently developing, and may in the future develop, our product candidates in combination with other therapies, which exposes us to additional risks.

Some of our or our collaborators' development efforts involve combinations of our product candidates with therapeutics that have been approved for marketing by the FDA. For example, the development of our RAS(ON) inhibitors includes combinations with existing therapies, including chemotherapy agents, an anti-EGFR agent and a PD-1 inhibitor. In the future our product candidates may be developed in combination with one or more additional approved therapies. Even if any of our product candidates 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 other therapy used in combination with our product candidate, or that safety, efficacy, manufacturing or supply issues could arise with these other 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. This could result in our own products being removed from the market or being less successful commercially. In addition, developing combination therapies using approved therapeutics, which we are doing and may continue to do for our product candidates, exposes us to additional clinical risks, such as the requirement that we demonstrate the safety and efficacy of each active component of any combination regimen we may develop, including any incremental benefits associated with our product candidates, which may prove challenging.

We or our collaborators may also evaluate our current or future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States or with approved cancer therapies at an unapproved dose and/or schedule, and/or with approved cancer therapies in unapproved indications. For example, the development of our RAS(ON) inhibitors includes combinations with other product candidates in our portfolio, including other RAS(ON) inhibitors. We will not be able to market and sell any of our product candidates in combination with any such cancer therapies, outside existing approved labels that do not ultimately obtain marketing approval.

If the FDA or similar regulatory authorities outside of the United States do not approve the other therapies we choose to evaluate in combination with any of our product candidates or revoke their approval of these other therapies, or if safety, efficacy, manufacturing or supply issues arise with these other therapies, we may be unable to obtain approval of or market or our product candidates.

We face significant competition, and if our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive. We are currently developing therapies that will compete, if approved, with other products and therapies that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other products and therapies, some of which we may not currently be aware of. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, product development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our

target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates obsolete. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or marketing approval or discovering, developing and commercializing products in our field before we do.

There are a number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. These treatments consist of small molecule drug products, biologics, cell-based therapies and traditional chemotherapy. Smaller and other early-stage companies may also prove to be significant competitors. In addition, academic research departments and public and private research institutions may be conducting research on compounds that could prove to be competitive.

There are several programs in clinical development targeting KRAS G12C, including programs directed at KRAS(OFF) G12C being conducted by Amgen Inc., Betta Pharmaceuticals Co., Ltd., Bristol Myers Squibb Company, Chengdu Huajian Future Technology Co. Ltd., D3 BIO, Inc., Eli Lilly, GenEros Biopharma Ltd., Genhouse Bio Co. Ltd., Guangzhou BeBetter Medicine Technology Co., Ltd., HUYA Bioscience, Innovent Biologics, Inc. (licensed to Genfleet Therapeutics), InventisBio, Jacobio Pharmaceuticals Co. Ltd., Jiangsu Hansoh Pharmaceutical Group Co., Ltd., Merck, Sharpe & Dohme LLC, Roche, Shanghai Junshi Biosciences Co., Ltd., Shanghai YingLi Pharmaceutical, Shouyao Holdings (Beijing) Co. Ltd. and Suzhou Zelgen Biopharmaceuticals. BridgeBio Pharma, Inc. and Frontier Medicines each have a dual KRAS(ON/OFF) G12C program in the clinic. There are also several clinical programs directed at KRAS G12D, including those being conducted by Astellas Pharma Inc., AstraZeneca, Eli Lilly, Genentech, Incyte Corporation, Jiangsu Hengrui Pharmaceuticals Company Ltd, Quanta Therapeutics, Tyligand Bioscience and Zelgen Biopharmaceuticals. In addition, there are a few clinical programs directed at KRAS G12V, including those being conducted by Affini-T Therapeutics and Yingkai Saiwei (Beijing) Biotechnology. Other clinical programs directed at mutant RAS, including pan-RAS inhibitors and Plk1 inhibitors, are being conducted, including those by Alaunos Therapeutics, Inc., BeiGene, Boehringer Ingelheim, Cardiff Oncology, Chugai Pharmaceutical Co., Ltd., Eli Lilly, Elicio Therapeutics, Gritstone bio, Inc., Moderna, Inc., Pfizer, Inc., Quanta Therapeutics, RasCal Therapeutics, Shanghai YingLi Pharmaceutical, Silenseed Ltd., Silexion Therapeutics and Targovax ASA. There are several programs in clinical development targeting SHP2, including those being conducted by Betta Pharmaceuticals Co., Ltd., Etern BioPharma (Shanghai) Co. Ltd., Genhouse Bio Co. Ltd., Hutchmed Ltd., HUYA Bioscience, InnoCare Pharma Ltd., Jacobio Pharmaceuticals Co. Ltd., Jiangsu Hansoh Pharmaceutical Group Co., Ltd., Nanjing Sanhome Pharmaceutical, Navire Pharma, Inc., a BridgeBio company (licensed to Bristol Myers Squibb Company), Novartis AG, Relay Therapeutics, Inc. (licensed to Roche), Shanghai Gopherwood Biotech Co., Ltd., and Shanghai Ringene Biopharma Co., Ltd. The above list includes corporate competitors that we are currently aware of and that are currently conducting clinical trials or marketing in geographies where we currently anticipate conducting clinical trials for our product candidates. However, companies operating in other geographies, smaller companies and companies with earlier stage programs may also prove to be significant competitors. In addition, academic research departments and public and private research institutions may be conducting research on compounds that could prove to be competitive.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain FDA, EMA or other marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness.

Third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our product candidates obsolete, less competitive or not economical.

Some of our programs focus on the discovery and development of "Beyond Rule of 5" small molecules. Such molecules can be associated with longer development timelines and greater costs compared to traditional small molecule drugs. Our "Beyond Rule of 5" product candidates may take longer to develop and/or manufacture relative to traditional small molecules, and we may not be able to formulate "Beyond Rule of 5" candidates for certain routes of administration.

We enlist various technologies and capabilities that give us chemical access to challenging sites on target proteins that generally are not accessible using conventional small molecule drug discovery approaches. For each target, we consider the specific structural, physico-chemical, functional and dynamic properties of the target and deploy the approach or approaches that appear most likely to

yield viable development candidates. The "Rule of 5" is a set of criteria used in pharmaceutical drug development to determine whether chemical compounds have certain physico-chemical properties that make them likely to be orally active drugs in humans. In some instances, the compounds we discover and develop are traditional small molecules (i.e., less than 500 daltons) with properties that generally satisfy conventional pharmaceutical "Rule of 5" criteria, while in other cases, they are larger (i.e., more than 500 daltons) "Beyond Rule of 5" (BRo5) compounds that do not satisfy these criteria. For example, our mTORC1 program and our RAS(ON) inhibitors each include pursuit of BRo5 compounds.

BRo5 compounds have been successfully pursued by many pharmaceutical companies. Examples of BRo5 compounds include natural products and semi-synthetic derivatives, peptidomimetics, macrocycles and degraders. However, larger molecular weight small molecules often cannot be formulated into orally absorbed drugs and also often face solubility, potency, bioavailability and stability challenges, among others. In addition, many of the commonly used predictive and other drug development tools are designed specifically for traditional "Rule of 5" small molecule drugs rather than BRo5 molecules, contributing to the difficulty and uncertainty of development of BRo5 compounds.

Due to their size and complexity, drug development of our BRo5 compounds may be slower and/or more expensive than drug development of traditional "Rule of 5" compounds, resulting in program delays, increased costs or failure to obtain regulatory approval in a commercially reasonable timeframe, if at all. Our competitors developing traditional small molecules in areas where we are developing BRo5 compounds could obtain regulatory approval and reach the market before we do. Even if we succeed in generating an approved drug from a BRo5 compound, it may be less convenient to administer, have higher grade and/or more frequent side effects or be more costly to manufacture and formulate than competing products on the market. The discovery and development of BRo5 small molecules may pose risks to us such as:

- BRo5 small molecules may present difficult synthetic chemistry and manufacturing challenges, including with any scale-up of our product candidates in sufficient quality and quantity;
- BRo5 small molecules may be challenging to purify, including with any scale-up of our product candidates in sufficient quality and quantity;
- BRo5 small molecules may present solubility challenges;
- BRo5 small molecules may present oral absorption challenges due to low passive permeability, and may not achieve acceptable oral bioavailability for development and may result in poor pharmaceutical properties for formulation development;
- BRo5 small molecules may present cell permeability challenges, especially with regards to lipophilicity, hydrogen bond donor and rotatable bond count, and high topological polar surface area;
- BRo5 small molecules may have a propensity to be substrates for efflux proteins such as the adenosine triphosphate (ATP) binding cassette (ABC) transporter protein family, including multidrug resistance protein 1. Cancer cells may overexpress these transporter proteins causing an increase in expulsion of BRo5 small molecules from the cell. For example, as the site of action of our RAS(ON) inhibitors is inside the cell, expulsion by these transporter proteins may decrease the effective concentration in the cell sufficiently to reduce target inhibition and thereby render a RAS-dependent tumor less susceptible to the inhibitory activity of a BRo5 small molecule, such as our product candidates;
- BRo5 small molecules may present central nervous system (CNS) penetration challenges due to low passive permeability and/or interaction with efflux transporters at the blood-brain barrier and this could limit sensitivity of CNS tumors to BRo5 small molecules;
- BRo5 small molecules may present formulation vehicle challenges for administration, such as intravenous and subcutaneous administration, due to aspects such as solubility and hydrophobicity;
- BRo5 small molecules may present stability and shelf-life limitations due to the incorporation of labile functionality in their scaffolds, including for example in the development of RMC-5552 which currently requires a cold chain storage of zero degrees Celsius; and
- BRo5 small molecules may present off-target toxicities due to physico-chemical properties such as lipophilicity, which is the ability to dissolve fats, oils and lipids, the presence of off-target pharmacophores in the molecule that can interact with other cellular proteins, or other characteristics that have not been fully characterized within a novel chemical scaffold or platform.

These and other risks related to our research and development of BRo5 small molecules may result in delays in development, an increase in development costs and/or the failure to develop any BRo5 small molecule to approval. As a result, our competitors may develop products more rapidly and cost effectively than we do if they are able to target the same indications as our product candidates using conventional small molecules. In particular, competitors may develop and commercialize products that compete with our RAS(ON) inhibitor product candidates.

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

The time required to obtain approval by the FDA, the EMA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that none of our current or future product candidates will ever obtain regulatory approval.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

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

This lengthy approval process as well as the unpredictability of clinical trial results may result in our or our future collaborators' failure to obtain regulatory approval to market any of our product candidates. The FDA, the EMA and other comparable foreign authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, this data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

In addition, even if we or our future collaborators were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we have sought, may not approve the prices we may desire to charge for our products, may grant approvals contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the prospects for our product candidates.

Further, we have not previously submitted an NDA to the FDA, or a Marketing Authorization Application (MAA) to the EMA or any other regulatory authority. We cannot be certain that any of our programs will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Clinical product development involves a lengthy and expensive process, with uncertain outcomes. We or our potential future collaboration partners may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current and future product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe or effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and future clinical trials involving our product candidates may not be successful.

We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to complete these clinical trials on the timelines we expect or otherwise delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- actions by regulators, institutional review boards (IRBs) or ethics committees, which may cause us or our investigators to not commence or conduct a clinical trial at a prospective trial site or at all sites and cause us to pause or stop an in-process clinical trial;
- delays in reaching, or failing to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations (CROs);
- delays in identifying, recruiting and training suitable clinical investigators;
- the number of patients required for clinical trials being larger than we anticipate;
- difficulty enrolling a sufficient number of patients for our clinical trials or enrollment in our trials being slower than we anticipate, including in both cases because appropriate patients must have the relevant mutations in the signaling pathways our therapies are designed to target;
- participants dropping out of our clinical trials or failing to return for post-treatment follow-up at a higher rate than we anticipate;
- patients or investigators not complying with our clinical trial protocols, particularly with respect to intermittent dosing, which we are evaluating for our product candidates;
- subjects experiencing severe or serious unexpected drug-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 product candidates;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- the supply or quality of materials for our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate;
- lack of adequate funding to continue a clinical trial, or costs being greater than we anticipate; and
- our collaborators may delay the development process by waiting to take action or focusing on other priorities.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which any such trial is being conducted, by the data safety monitoring board for such trial or by the FDA or other 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 regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our product candidates.

Further, conducting clinical trials in foreign countries, as we or our collaborators may do for our 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, relevant to these foreign countries.

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 their 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. 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 marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, for our product candidates and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

If we or our collaborators experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate revenues from any of these product candidates will be delayed. In addition, any delays in completing clinical trials for our product candidates will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change, and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation (CTR), which was adopted in April 2014 and repealed the EU Clinical Trials Directive, became applicable on January 31, 2022, with a three-year transition period. The CTR provides for a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the clinical trial application (CTA) has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. As of February 1, 2025, all clinical trials (including those which are ongoing) in the EU are subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as our CROs, may impact our development plans.

The United Kingdom's (UK) regulatory framework in relation to clinical trials is derived from pre-existing EU legislation (as implemented into UK law, through secondary legislation). Whether the regulation of clinical trials in the UK will mirror the (EU) CTR in the long term is not yet certain; however, in December 2024, the UK government introduced a legislative proposal, the Medicines for Human Use (Clinical Trials) Amendment Regulations 2024, that, if implemented, will replace the current regulatory framework for clinical trials in the UK. The legislative proposal aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered. The UK government has provided the legislative proposal to the UK Parliament for its review and approval. Once the legislative proposal is approved (with or without amendment), it will be adopted into UK law which is expected in early 2026. A decision by the UK government not to closely align any new legislation with the new approach that has been adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to countries in the EU.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

Many of the factors described above that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the development of our product candidates being stopped early.

Interim, "topline" and preliminary data from our clinical trials may differ materially from the final data.

From time to time, we may disclose interim data from our clinical trials. For example, we have reported interim Phase 1 single agent clinical data for daraxonrasib, elironrasib and zoldonrasib. In each case, this interim data included a limited number of patients and time of exposure to the study drug. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes

may materially change as patient enrollment continues and more data on existing patients become available. When a clinical trial is ongoing, the final results from the trial may be materially different from those reflected in any interim data we report.

From time to time, we may also publicly disclose preliminary or "topline" data from our clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, including decisions to initiate pivotal clinical trials based on then-available data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same clinical trials, or different conclusions or considerations may qualify such topline results once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and the value of our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically a summary of extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed.

Our current or future product candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could delay or halt their clinical development, prevent their marketing approval, limit their commercial potential or result in significant negative consequences.

Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable or clinically unmanageable side effects could occur and cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. Any treatment-related side effects could also affect patient recruitment in the relevant trial or other current or future trials involving the same product candidate or other product candidates, or the ability of enrolled patients to complete the trial, and could result in potential product liability claims.

For example, the safety and tolerability data we have released from the daraxonrasib, elironrasib and zoldonrasib studies included adverse events (AEs), including serious adverse events (SAEs) and AEs that led to dose interruption or reduction.

Although our current and future product candidates will undergo safety testing to the extent possible and, where applicable, under such conditions discussed with regulatory authorities, not all adverse effects of drugs can be predicted or anticipated.

Unforeseen side effects could arise either during clinical development or, if such side effects are rarer, following approval or commercialization after exposure to additional patients. So far, we have not demonstrated that our product candidates are safe in humans, and we cannot predict if ongoing or future clinical trials will do so.

Furthermore, certain of our product candidates are currently being, and may in the future be, co-administered with approved or experimental therapies. These combinations may have additional side effects, including those that could lead us to discontinue the studies. The uncertainty resulting from the use of our product candidates in combination with other therapies may make it difficult to accurately predict side effects in future clinical trials.

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

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;

- we may be required to implement a risk evaluation and mitigation strategy (REMS) or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved. In addition, if one or more of our product candidates prove to be unsafe, our entire technology platform and pipeline could be affected.

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

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

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products was published in April 2023, and would, among other things, potentially reduce the duration of regulatory data protection and revise the eligibility for expedited pathways. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may, however, have a significant long-term impact on the biopharmaceutical industry.

The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we or our potential future collaboration partners ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we or potential future collaboration partners experience delays in obtaining approval or if we fail to obtain approval of any of our current or future product candidates, the commercial prospects for those product candidates may be harmed.

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

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

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

Adverse events in the field of oncology or the biopharmaceutical industry could damage public perception of our current or future product candidates and negatively affect our business.

The commercial success of our products will depend in part on public acceptance of the use of targeted cancer therapies. While a number of targeted cancer therapies have received regulatory approval and are being commercialized, our approach to targeting cancer cells carrying tumor causing mutations, including oncogenic RAS(ON) pathway mutations, is novel and unproven. Adverse events in clinical trials of our product candidates, or post-marketing activities, or in clinical trials of others developing similar products or that are related to approved targeted therapies, particularly those targeting oncogenic RAS pathway mutations, including sotorasib and adagrasib and the resulting publicity, as well as any other adverse events in the field of oncology that may occur in the future, could result in a decrease in demand for any product that we may develop. If public perception is influenced by claims that the use of cancer therapies is unsafe, whether related to our therapies or those of our competitors, our product candidates or products, if approved, may not be accepted by the general public or the medical community.

Future adverse events in oncology or the biopharmaceutical industry could also result in greater government regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our current or future product candidates.

Even if we or our potential future collaboration partners receive marketing approval of a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products, if approved.

Any marketing approvals that we or our potential future collaboration partners receive for any current or future product candidate may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require REMS as a condition of approval of any product candidate, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import and export and record keeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practice (cGMP) or similar foreign requirements and Good Clinical Practice (GCP) for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with any

approved candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, untitled and warning letters, or holds on clinical trials;
- refusal by the FDA or comparable foreign authorities 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 the product; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our or our potential future collaboration partners' ability to commercialize our product candidates and generate revenue and 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 enacted that could prevent, limit or delay marketing approval of a product. We 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 or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our current or future product candidates receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community to be a viable product. For example, current approved immunotherapies, and other cancer treatments like chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these therapies. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy;
- adoption of a companion diagnostic and/or complementary diagnostic (if any); and
- the prevalence and severity of any side effects.

The market opportunities for any of our current or future product candidates, if and when approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Cancer therapies are sometimes characterized as first-line, second-line or third-line. When cancer is detected early enough, first-line therapy— usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these— is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We expect to initially seek approval of our product candidates as a therapy for patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the cancers we are targeting, including those with the necessary mutations, may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current programs or future product candidates may be limited, if and when approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve commercial success without obtaining marketing approval for additional indications, including to be used as first-line therapy.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies.

The regulations that govern marketing approvals, pricing and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing government control even after initial approval is granted. As a result, we or our potential future collaboration partners might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay the commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our and our potential future collaboration partners' ability to commercialize any product candidates, whether as a single agent or combination therapy, successfully will also depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from government authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our programs.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, as the process is time-consuming and costly, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Additionally, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States, which may result in coverage and reimbursement for drug products that can differ significantly from payor to payor. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of existing laws that restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and requiring substitutions of generic products and/or biosimilars. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We cannot be sure that coverage will be available for any of our product candidates, even if approved, and, if coverage is available, the level of reimbursement. These third-party payors are also examining the cost-effectiveness of drugs in addition to their safety and efficacy. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we or our potential third party collaborators may not be able to successfully commercialize any product candidate even if approved.

We may fail to select or capitalize on the most scientifically, clinically and commercially promising or profitable drug candidates including mutant RAS(ON) targets.

We have limited technical, managerial and financial resources to determine which of our potential assets, including our RAS(ON) inhibitors, should be advanced into further preclinical development, initial clinical trials, later-stage clinical development and potential commercialization. From our RAS(ON) inhibitors, we have selected RMC-6236, our RAS(ON) multi-selective inhibitor, RMC-6291, our RAS(ON) G12C-selective inhibitor and RMC-9805, our inhibitor targeting KRAS(ON) G12D as the first RAS(ON) inhibitor candidates for clinical evaluation. In making these prioritization decisions and selecting development candidates from our preclinical assets, we may make incorrect determinations. Our decisions to allocate our research and development, management and financial resources toward particular development candidates or therapeutic areas, including the RASolute 302 study, the RASolve 301 study and other pivotal trials, may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate development programs may also be incorrect and could cause us to miss valuable opportunities.

We may not be successful in our efforts to identify or discover other product candidates and may fail to capitalize on programs, product candidates or indications or lines of therapy for which there is a greater likelihood of success or that may present a greater commercial opportunity.

The success of our business depends upon our ability to identify, develop and commercialize product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources, and we may fail to identify potential product candidates for numerous reasons.

Additionally, because we have limited resources and because of the decisions we make based on our observations from the results of earlier-stage clinical trials, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications or lines of therapy that later prove to have a greater likelihood of success or for which there is greater commercial potential. For example, we may design our clinical trials, including our pivotal clinical trials, based on our observations from earlier-stage clinical trials. In doing so, we may make decisions regarding our study design, including our selection of the inclusion and exclusion criteria and endpoints, as well as our selection of dose and dose schedule and other factors, for those trials, while other study designs and dosing regimens may have a greater likelihood of success.

However, the advancement of a particular product candidate may ultimately prove to be unsuccessful or less successful than another program in our pipeline that we might have chosen to pursue on a less aggressive basis. Our estimates regarding the potential market for our product candidates could be inaccurate, and our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate.

We may need to use existing commercial diagnostic tests or develop, or enter into a collaboration or partnership to develop, novel complementary diagnostics and/or novel companion diagnostics for some of our current or future product candidates. If we or our partners are unable to successfully develop these companion diagnostics or complementary diagnostics, or experience significant delays in doing so, we may not realize the full commercial potential of our future product candidates.

As one of the key elements of our product development strategy, we seek to identify cancer patient populations that may derive meaningful benefit from our current or future product candidates. Because predictive biomarkers may be used to identify the right patients for our programs and our current or future product candidates, we believe that our success may depend, in part, on our ability to use existing diagnostic tests from third parties or develop novel complementary diagnostics and/or novel companion diagnostics in collaboration with partners.

In the event that novel tests will need to be developed, we have little experience in the development of diagnostics. We expect to rely on partners in developing appropriate diagnostics to pair with our current or future product candidates. We may be unsuccessful in entering into or maintaining collaborations for the development of companion diagnostics for use with our current or future product candidates in our markets of interest.

Complementary diagnostics and companion diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval, clearance or certification prior to commercialization. In addition, 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. Companion diagnostics are developed in conjunction with clinical programs for the associated therapeutic product, 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, such as a biomarker, that the companion diagnostic was developed to detect.

If we, our partners, or any third parties that we engage to assist us, are unable to successfully develop complementary diagnostics and/or companion diagnostics for our product candidates and any future product candidates, or we experience delays in doing so:

- the development of our product candidates and any other future product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;
- we may be unable to obtain approval for any of our product candidates for which the FDA or foreign regulatory authority has determined a companion diagnostic is required; and
- we may not realize the full commercial potential of our product candidates and any other future product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify, or it takes us longer to identify, patients who are likely to benefit from therapy with our products, if approved.

Even if we or our current or future partners are successful in the development of diagnostics for use with our current or future product candidates, there are also risks associated with the commercial supply of these diagnostics.

We may seek and fail to obtain fast track or breakthrough therapy designations for our current or future product candidates. Even if we are successful, these programs may not lead to a faster development or regulatory review process, and they do not guarantee we will receive approval for any product candidate.

If a product is intended for the treatment of a serious or life-threatening condition, and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for fast track designation. Specifically, drugs are eligible for fast track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. 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 product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. An NDA submitted for a fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

The FDA has broad discretion whether to grant fast track designation, so, even if we believe a particular product candidate is eligible for this designation, the FDA may reach a different conclusion and not grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind any fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

We may also seek breakthrough therapy designation for our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, increased interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs and biologics designated as breakthrough therapies also receive the same benefits associated with fast track designation, including eligibility for rolling review of a submitted NDA, if the relevant criteria are met. Like fast track designation, breakthrough therapy designation is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and

does not assure ultimate approval by the FDA. In addition, even if a product candidate qualifies as a breakthrough therapy, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Jurisdictions where we may seek to pursue product candidates outside of the United States have processes similar to the breakthrough designation and fast track processes described above, and to the extent we or our collaborators desire to enter these markets, we will face similar risks and challenges as those described in the United States.

We may attempt to secure approval from the FDA through the use of the accelerated approval pathway. If we are unable to obtain this approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary regulatory approvals. Even if we receive accelerated approval from the FDA, 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 any accelerated approval we have obtained.

We may in the future seek accelerated approval for one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a 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. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. 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 or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, in December 2022, President Biden signed an omnibus appropriations bill to fund the U.S. government through fiscal year 2023. The omnibus bill included the Food and Drug Omnibus Reform Act of 2022, which, among other things, provided the FDA new statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval for our product candidates, there can be no assurance that such application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require the conduct of further studies prior to considering our (or one of our potential future collaboration partners') applications or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period until commercialization of such product candidate, if at all, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may seek orphan drug designation for our product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

As part of our business strategy, we may seek orphan drug designation for our product candidates. Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs or, in the EU, orphan medicinal products. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in the EU, the European Commission grants orphan medicinal product designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan medicinal product designation application. Orphan medicinal product designation is intended to promote the development of medicines (1) that are intended for the diagnosis, prevention or treatment of

life-threatening or chronically debilitating conditions where (2) either (a) such conditions affect no more than 5 in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the investment needed for its development; and (3) for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or if such method exists, the product would be a significant benefit to those affected). In the EU, orphan designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or foreign authorities from approving another marketing application for the same drug for the same disease or condition for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in the EU. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

We may be unsuccessful in obtaining orphan drug designation for our product candidates. In addition, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different therapies can be approved for the same disease or condition. Even after an orphan drug is approved, the FDA or comparable foreign authorities can subsequently approve the same drug for the same disease or condition if the FDA or comparable foreign authorities conclude that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the disease or condition for which it received orphan designation. Moreover, 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 quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek orphan drug designation for applicable indications for our current and any future product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations, including marketing exclusivity.

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

We face an inherent risk of product liability as a result of the clinical testing of product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any of our product candidates causes or is perceived to cause injury or is found to be otherwise unsuitable during clinical 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 or a breach of warranties. 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 commercialization of any approved products. Even successful defense would require significant financial and management resources.

Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any approved product;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- exhaustion of available insurance and our capital resources and potential increases in our insurance premiums and/or retention amounts; and
- our inability, or limitations on our ability, to commercialize any product.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaboration partners.

Insurance coverage is increasingly expensive. We may not be able to maintain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all. Our insurance policy contains 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. Even if our agreements with any current or future collaborator entitle us to indemnification against losses, such indemnification is limited and may not be available or adequate should any claim arise.

Healthcare legislative reform measures may significantly impact our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act (the ACA) was passed, which substantially changed the way healthcare is financed by both government and private insurers, and significantly impacts the U.S. pharmaceutical industry. 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 and taxes on manufacturers of certain branded prescription drugs.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. In June 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

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

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. In August 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new manufacturer discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. In August 2024, HHS announced the negotiated prices for the initial ten drugs, which will first be effective in 2026, and in January 2025, HHS announced the second set of drugs that will be subject to price negotiations. Because the Medicare drug price negotiation program is currently subject to legal challenges, and for other reasons, it is currently unclear how the IRA will be effectuated, and the impact of the IRA on our business and the pharmaceutical industry cannot yet be fully determined.

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

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for our product candidates. We cannot determine how changes in regulations, statutes, policies or interpretations when and if issued, enacted or adopted may affect our business in the future.

Disruptions at the FDA and other government agencies caused by funding shortages, staffing levels or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA and foreign regulatory agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA and foreign regulatory agencies have fluctuated in recent years as a result.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, 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. Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. More recently, there have been layoffs and resignations at the FDA and other federal agencies. If a prolonged government shutdown occurs or the FDA or other agencies experiences other delays due to staffing shortages or otherwise, it could significantly impact the ability of those agencies to timely review and process our regulatory submissions.

We are subject to stringent privacy laws, information security policies and contractual obligations governing the use, processing and transfer of personal information.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous federal, state and foreign laws, requirements and regulations governing the collection, use, disclosure, retention and security of personal information, such as information that we may collect in connection with clinical trials in the United States and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Further, various states have implemented certain data privacy and security laws and regulations that impose restrictive requirements regulating the use and disclosure of health-related and other personal information. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the CCPA) requires certain businesses that process personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete and correct their personal information, or opt-out of certain disclosures of their personal information; and enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Similar laws have been passed in other states, and are continuing to be proposed at the state and the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA or the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

State laws and regulations are not necessarily preempted by federal laws and regulations, such as HIPAA, particularly if a state affords greater protection to individuals than federal law. Where state laws are more protective, we must comply with the stricter provisions.

In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and data we receive, use and share, potentially exposing us to additional expense, adverse publicity and liability. Legal requirements relating to the collection, storage, handling, and transfer of personal information and personal data continue to evolve and may result in increased public scrutiny and escalating levels of enforcement, sanctions and increased costs of compliance.

The processing of personal data in the European Economic Area (EEA) is governed by the General Data Protection Regulation (the GDPR). The GDPR imposes stringent requirements for controllers and processors of personal data. The GDPR applies extraterritorially, and we may be subject to the GDPR because of our data processing activities that involve the personal data of individuals located in the EEA, or in the context of our activities within the EEA, such as in connection with any EEA clinical trials. The GDPR may impose additional obligations and liability in relation to the personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with its requirements. This may be onerous and may interrupt or delay our development activities. If we or our vendors fail to comply with the GDPR and the applicable national data protection laws of the EEA member states, or if regulators assert we have failed to comply with these laws, it may lead to regulatory enforcement actions, which can result in, among other things, monetary penalties of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the noncompliant undertaking for the preceding financial year, whichever is higher, and other administrative penalties. The GDPR also imposes strict rules on the transfer of personal data out of the EEA to the United States and other third countries that have not been found to provide adequate protection to such personal data, and the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. Case law from the Court of Justice of the European Union states that reliance on the standard contractual clauses – a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism – alone may not necessarily be sufficient in all circumstances, and that transfers must be assessed on a case-by-case basis.

The European Commission adopted its Adequacy Decision in relation to the EU-U.S. Data Privacy Framework (the DPF) in July 2023, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We currently rely in part on the EU standard contractual clauses and the UK Addendum to the EU standard contractual clauses, as relevant, to transfer personal data outside the EEA and the UK, including to the United States. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the U.S. and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes, and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required timeframes.

We must also comply with the UK General Data Protection Regulation, which, together with the UK Data Protection Act 2018, retains the GDPR in UK national law (collectively, the UK GDPR). The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of £17.5 million or 4% of global turnover of a noncompliant undertaking's global annual revenue for the preceding financial year. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U.S. entities self-certified under the DPF. We may incur liabilities, expenses, costs and other operational losses under the GDPR and privacy laws of the applicable EU and EEA Member States and the UK in connection with any measures we take to comply with them. As we continue to expand into other foreign countries and jurisdictions, we may also be subject to additional laws and regulations that may affect how we conduct business.

Compliance with U.S. and international data protection laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Penalties for violations of these laws vary and may be significant. Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. In addition, we rely on third-party vendors to collect, process and store data on our behalf and we cannot guarantee that such vendors are in compliance with all applicable data protection laws and regulations. Our or our vendors' failure to comply with U.S. and international data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), private litigation and adverse publicity. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity.

Our business and operations, or those of our CROs or other third parties, may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity, which could materially affect our business, results of operations and financial condition.

We receive, generate and store significant and increasing volumes of sensitive information, such as health-related information, clinical trial data, proprietary business information and the personal information of our employees and contractors (collectively, Confidential

Information). We face a number of risks related to protecting the information technology systems we rely on and this Confidential Information, including loss of access risk, inappropriate use or disclosure, inappropriate modification and the risk of our being unable to adequately monitor, audit and modify our controls over our Confidential Information. This risk extends to the information technology systems and information of any collaboration partners, medical institutions, clinical investigators, CROs, contract laboratories and other third parties involved in our business. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and Confidential Information.

Despite the implementation of security measures, our information technology systems, as well as those of CROs or other third parties with which we have relationships, are vulnerable to attack, interruption and damage from computer viruses and malware (e.g., ransomware), malicious code, misconfigurations, "bugs" or other vulnerabilities, unauthorized access, natural and manmade disasters, terrorism, war and telecommunication and electrical failures, malfeasance by external or internal parties, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors and human error (e.g., social engineering and phishing). Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the technologies used to obtain unauthorized access to, or to sabotage or disrupt, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. We may not be able to anticipate all types of security threats, and, even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our and our service providers' employees who are (and may continue to be) working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. The White House, the Securities and Exchange Commission (the SEC) and other regulators have also increased their focus on companies' cybersecurity vulnerabilities and risks. Further, although we have implemented policies regarding limited permitted use of generative artificial intelligence (AI) by our employees, Confidential Information could be leaked, disclosed or revealed as a result of or in connection with our employees' use of generative AI technologies.

We, our CROs and certain of our service providers are, from time to time, subject to cyberattacks and security incidents. While we have not to our knowledge experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our or our critical third parties' operations, it could result in delays and/or material disruptions of our research and development programs, our operations and ultimately, our financial results. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their information technology systems could also adversely impact our business. Further, due to the current political uncertainty involving Russia and Ukraine, there is an increased likelihood that the tensions could result in cyberattacks or cybersecurity incidents that could either directly or indirectly impact our or our critical third parties' operations. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of Confidential Information, the costs associated with the investigation, remediation and potential notification of the breach to counterparties and data subjects could be material, we could incur liability due to delays in the development and commercialization of our product candidates or other business activities, and we may be exposed to reputational harm, litigation, regulatory investigations and enforcement, fines and penalties, or increased costs of compliance and system remediation.

Our existing general liability and cyber liability insurance policies may not cover, or may cover only a portion of, any potential claims related to security breaches to which we are exposed or may not be adequate to indemnify us for all or any portion of liabilities that may be imposed. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or breach or that the insurer will not deny coverage of any future claim. If the information technology systems of our CROs or other service providers were to fail, or become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

Risks related to reliance on third parties

We may depend on collaborations with other third parties for the development and commercialization of our product candidates in the future. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

In the future, we may form or seek other strategic alliances, joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates.

Collaborations involving our current and future product candidates may pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may have incentives that are different than ours;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, 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 products or product candidates;
- collaborators with marketing, manufacturing or distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities as it relates to our product candidates or products;
- collaborators may not properly prosecute, maintain, enforce or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings;
- collaborators may own or co-own intellectual property covering products that result from our collaboration with them, and in such cases, we may not have the exclusive right to develop, license or commercialize this intellectual property;
- disputes may arise with respect to ownership of any intellectual property developed pursuant to our collaborations;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources; and
- if a current or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under our collaboration could be delayed, diminished or terminated, including if the partner in such a business combination has products that compete with ours.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our or their existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following entry into a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our current or future product candidates could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition, and results of operations.

We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with additional pharmaceutical and biotechnology companies with respect to development and potential commercialization. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for other collaborations will depend, among other things, upon our assessment of the

collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish one or more strategic partnerships or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

The terms of any collaboration agreement we enter into may restrict us from entering into future agreements on certain terms with potential collaborators, which may limit our ability to find additional collaborators in the future or adversely impact the terms of these future collaborations.

In addition, business combinations among pharmaceutical and biotechnology companies have in the past and may in the future result in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Amgen or future collaborators or strategic partners may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our product candidates. Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

We rely on third parties to conduct the clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our product candidates.

We do not have the ability to independently conduct clinical trials. We and any collaboration partners who may conduct clinical trials involving our product candidates rely on medical institutions, clinical investigators, CROs, contract laboratories, and other third parties to conduct or otherwise support these clinical trials, all of which we refer to herein as our clinical trials. We and our collaborators rely heavily on these parties for execution of clinical trials and control only certain aspects of their activities. In addition, we have limited control over the activities of our collaborators who may conduct clinical trials involving our product candidates. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of these responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled and warning letters or enforcement actions that may include civil penalties or criminal prosecution.

We, our collaborators and the other third parties involved in our clinical trials are required to comply with regulations and requirements, including GCP, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the competent authorities of the EU member states and comparable foreign regulatory authorities for any drugs in clinical development. The FDA and comparable foreign regulatory authorities enforce GCP requirements through periodic inspections of clinical trial sponsors, principal investigators

and trial sites. If we, our collaborators or other third parties fail to comply with applicable GCP, 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 clinical trials before approving our marketing applications. Upon inspection, the FDA or comparable foreign authorities may determine that any of our current or future clinical trials do not comply with GCP. In addition, our clinical trials must be conducted with product candidates produced under cGMP regulations and similar regulatory requirements outside the United States. Our failure or the failure of third parties to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a United States government-sponsored database, ClinicalTrials.gov, within specific timeframes. Similar disclosure requirements may exist in foreign jurisdictions. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

We have participated and in the future may participate in clinical collaborations where a partner is responsible for conducting a clinical trial involving our product candidates. These collaborators may be commercial entities or investigator-sponsored or initiated studies that use our product candidates. Although we intend to design the clinical trials for our product candidates, or be involved in the design when other parties sponsor the trials, because these collaborators will have primary responsibility for the conduct of these trials, many important aspects of our clinical development for these trials, including their conduct and timing, is outside of our direct control.

Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with third parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Third parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- have incentives that are different than ours;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs or other third parties involved in our clinical trials do not perform these trials in a satisfactory manner, breach their obligations to us, or fail to comply with regulatory requirements, the development, marketing approval and commercialization of our product candidates may be delayed, we may not be able to obtain marketing approval and commercialize our product candidates, or our development program may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by third parties involved in our clinical trials, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with our CROs or other third parties involved in our clinical trials terminate, we may not be able to enter into arrangements with alternative CROs or other third parties on commercially reasonable terms, or at all. If CROs or other third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs or other third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates.

We rely on third parties to manufacture preclinical and clinical drug supplies, and we intend to rely on third parties to produce commercial supplies of any approved product, which increases the risk that we will not have sufficient quantities of these product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of preclinical, clinical or commercial supplies of the product candidates that we are developing or evaluating in our development programs. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a preclinical, clinical or commercial scale. We rely on third parties for supply of our preclinical and clinical drug supplies (including key starting and intermediate materials), and our strategy is to outsource all manufacturing of our product candidates and products to third parties.

In order to conduct clinical trials of product candidates, we will need to have them manufactured in potentially large quantities. Our third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our clinical drug supplies (including key starting and intermediate materials) in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time. For example, ongoing data on the stability of our product candidates may shorten the expiry of our product candidates and lead to clinical trial material supply shortages, and potentially clinical trial delays. If these third-party manufacturers are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained.

Some of our third-party suppliers are currently our sole source of drug supplies (including key starting and intermediate materials) and, as a result, an issue with one of these suppliers may impact our development or commercial plans. Our use of new third-party manufacturers or suppliers increases the risk of delays in production or insufficient supplies of our product candidates (and the key starting and intermediate materials for such product candidates) as we transfer our manufacturing technology to these manufacturers or suppliers and as they gain experience manufacturing or producing our product candidates (and the key starting and intermediate materials for these product candidates).

Even after a third-party manufacturer has gained significant experience in manufacturing our product candidates (or the key starting and intermediate materials for such product candidates), or even if we believe we have succeeded in optimizing the manufacturing process, there can be no assurance that such manufacturer will produce sufficient quantities of our product candidates (or the key starting and intermediate materials for such product candidates) in a timely manner or continuously over time, or at all. We may be delayed if we need to change the manufacturing process used by a third party. Further, if we change an approved manufacturing process, then we may be delayed if the FDA or a comparable foreign authority needs to review the new manufacturing process before it may be used.

Reliance on third-party manufacturers for preclinical, clinical and commercial supplies entails risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us

We do not currently have any agreements with third-party manufacturers for long-term commercial supply. In the future, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of any of our product candidates, or may be unable to do so on acceptable terms. Even if we are able to establish and maintain arrangements with third-party manufacturers for commercial supply, reliance on third-party manufacturers entails risks, including those described above.

Third-party manufacturers may not be able to comply with cGMP requirements or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and/or criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

Our future product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP requirements particularly for the development of monoclonal antibodies, and that might be capable of manufacturing for us.

Additionally, in January 2024, there was Congressional activity, including the introduction of the BIOSECURE Act in the House of Representatives and a substantially similar Senate bill. In September 2024, the House of Representatives of the prior Congress (the 118th Congress) passed the BIOSECURE Act, but the Senate never voted on it. It is unclear whether the current Congress (the 119th Congress) will introduce the BIOSECURE Act or similar legislation in this congressional session and, if so, how the scope, prohibitions or designated biotechnology companies of concern may differ from the version of the BIOSECURE Act passed by the House in the prior 118th Congress. If these bills became law, or similar laws are passed, they would have the potential to severely restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies "of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We do business with companies in China, including some named in these bills, and it is possible some of our contractual counterparties could be impacted by the legislation described above.

If the third parties that we engage to supply any materials or manufacture product for our preclinical tests and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers, and we may be unable to obtain replacement supplies on terms that are favorable to us or at all. In addition, if we are not able to obtain adequate supplies of our product candidates or the substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our current and anticipated future dependence upon others for the manufacture of our product candidates (or the key starting and intermediate materials for such product candidates) may adversely affect our future profit margins and our ability to develop product candidates and commercialize any products that receive marketing approval on a timely and competitive basis.

Our future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act (FCA), which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any products for which we obtain marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- the federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim 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 FCA;
- HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statutes or specific intent to violate them;
- the Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (defined to include physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous or related foreign, state or local laws and regulations, including anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-government third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Because of the breadth of the laws described above and the narrowness of the statutory exceptions and regulatory safe harbors available under them, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our business arrangements with third parties comply with applicable healthcare laws, as well as responding to investigations by government authorities, can be time- and resource-consuming and can divert management's attention from the business.

If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could harm our ability to operate our business and our financial results. Further, if the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Risks related to intellectual property

If we and our collaborators are unable to obtain and maintain sufficient patent and other intellectual property protection for our product candidates and technology, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any of our current or future product candidates.

Our success depends in significant part on our ability and the ability of our collaborators to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to our product candidates and technology and to operate our business without infringing, misappropriating, or otherwise violating the intellectual property rights of others. If we and our collaborators are unable to obtain and maintain sufficient intellectual property protection for our product candidates or the product candidates that we may identify, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize product candidates similar or identical to ours, and our ability (and the ability of our collaborators) to successfully commercialize our product candidates may be impaired. Our patent coverage with respect to our clinical and preclinical programs is limited, and we can provide no assurance that any of our current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. Failure to obtain such issued patents could negatively impact our and our collaborators' ability to develop or commercialize any of our product candidates or technology.

We seek to protect our proprietary positions by, among other things, filing patent applications in the United States and abroad related to our current product candidates and the product candidates that we may identify. Obtaining, maintaining, defending and enforcing pharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we have failed or will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing, prosecution and maintenance of patent applications, or to maintain the rights to patents licensed to or from third parties.

Although we enter into confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, 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 ability to seek patent protection. Further, we may not be aware of all third-party intellectual property rights

potentially relating to our product candidates. 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 approximately 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal, technological and factual questions and has, in recent years, been the subject of much debate and litigation throughout the world. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. The subject matter claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Therefore, our pending and future patent applications may not result in patents being issued in relevant jurisdictions that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive product candidates, and, even if our patent applications issue as patents in relevant jurisdictions, they may not issue in a form that will provide us with any meaningful protection for our product candidates or technology, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Additionally, our competitors may be able to circumvent our patents by developing similar or alternative product candidates or technologies in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office (the USPTO) or become involved in opposition, derivation, revocation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others, or other proceedings in the USPTO or applicable foreign offices that challenge priority of invention or other features of patentability. An adverse determination in any such submission, proceeding or litigation could result in loss of exclusivity or freedom to operate, patent claims being narrowed, invalidated or held unenforceable, in whole or in part, or limits on the scope or duration of the patent protection of our product candidates, all of which could limit our ability to stop others from using or commercializing similar or identical product candidates or technology to compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications were threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates, or could negatively impact our ability to raise funds necessary to continue our research programs or clinical trials. Such proceedings could also result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

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

We have entered into license agreements with third parties. If we or a third party fail to comply with the obligations in the agreements under which we license intellectual property rights to or from third parties, or these agreements are terminated, or we otherwise experience disruptions to business relationships with our licensors or licensees, our competitive position, business, financial condition, results of operations and prospects could be harmed.

In addition to patent and other intellectual property rights we own or co-own, we have licensed, and may in the future license, patent and other intellectual property rights to and from other parties. Licenses may not provide us with exclusive rights to use the applicable intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our products and technology in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products or technologies.

In addition, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications or to maintain, defend and enforce the patents that we license to or from third parties, and we may have to rely on our partners to fulfill these responsibilities.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, the licensor may have the right to terminate the license. If these agreements are terminated, the underlying patents fail to provide the intended exclusivity or we otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business or be prevented from developing and commercializing our product candidates, and competitors could have the freedom to seek regulatory approval of, and to market, products identical to ours. Termination of these agreements or reduction or elimination of our rights under these agreements may also result in our having to negotiate new agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis.

In addition, if any of the research resulting in certain of our owned and/or in-licensed patent rights and technology were funded in part by the U.S. federal or state governments, the government would have certain rights, including march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and certain provisions in intellectual property license agreements may be susceptible to multiple interpretations. Disputes may arise between us and our licensing partners regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which technology and processes of one party infringe on intellectual property of the other party that are not subject to the license agreement;
- rights to sublicense patent and other rights to third parties;
- rights to transfer or assign the license;
- any diligence obligations with respect to the use of the licensed technology in relation to development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property; and
- the effects of termination.

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 intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could harm our business, financial condition, results of operations and prospects. Moreover, 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 product candidates.

In addition, if our licensors or licensees failed to abide by the terms of the license or failed to prevent infringement by third parties or if the licensed patents or other rights were found to be invalid or unenforceable, our business, competitive position, financial condition, results of operations and prospects could be materially harmed.

If we are unable to obtain licenses from third parties on commercially reasonable terms or at all, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. More established companies may have a competitive advantage over us due to their size, capital resources and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual

property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to license needed technology, or if we are forced to license this technology on unfavorable terms, our business could be materially harmed.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might subject us to infringement claims or adversely affect our ability to develop and market our 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 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 product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with the earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by third parties 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 our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending 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, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve any infringement claims. If we fail in any of these disputes, in addition to being forced to pay damages, which may be significant, 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 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.

Patent terms may be inadequate to protect our competitive position on 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 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 current and future product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications and biosimilars. 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 product candidates similar or identical to ours for a meaningful amount of time, or at all.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our owned or licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union and certain other countries. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

In addition, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book). We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated NDA filed with the FDA to obtain permission to sell a generic version of such product candidate.

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

Filing, prosecuting, maintaining, defending and enforcing patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and enforcement practices of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. The current conflict between Russia and Ukraine may also make it difficult or impossible to continue to prosecute patent applications or maintain patents in those countries or other affected territories. For example, in March 2022, a decree was adopted by the Russian government allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement or protection of patents, trade secrets and other intellectual property, 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. 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. Proceedings to enforce our intellectual property 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 and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many foreign countries, including some European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we (or one of our collaborators) are compelled to grant a license (or sublicense) to a third party, which could materially diminish the value of the applicable patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Obtaining and enforcing patents in the pharmaceutical industry is inherently uncertain, due in part to ongoing changes in the patent laws. For example, in the United States, depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents, and interpretation thereof, could change in ways that could weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing or future patents, or that affect the term of our or our licensors' or collaborators' patents. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Therefore, there is increased uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, as well as uncertainty with respect to the value of patents once obtained.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. For example, 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 Leahy-Smith 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. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first inventor-to-file provisions. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. Similarly, statutory or judicial changes to the patent laws of other countries may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents.

On June 1, 2023, the European Patent Package (the EU Patent Package) regulations were implemented with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (the UPC), for litigation involving European patents. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC provides our competitors with a new forum to centrally revoke our European patents, and allows for the possibility of a competitor 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 provided by the UPC. As the UPC is a relatively new court system, there is limited precedent for the court, increasing the uncertainty of any litigation. We will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits, if any, of the new unified court.

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 if we fail to comply with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other fees are required to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. In certain circumstances, we rely on our licensors and collaborators to pay these fees. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application and prosecution process. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. While an inadvertent lapse can in some cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the relevant market(s) with similar or identical products or technology, which would harm our business, financial condition, results of operations and prospects.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful, and issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged.

Competitors and other third parties may infringe or otherwise violate our issued patents or other intellectual property or the patents or other intellectual property of our licensors. In addition, our patents or the patents of our licensors may become involved in inventorship or priority disputes. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. To counter infringement or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Our ability to enforce patent rights also depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated, held unenforceable or interpreted narrowly. Additionally, we may determine it is impractical or undesirable to enforce our intellectual property against some third parties.

If we were to initiate legal proceedings against a third party to enforce a patent directed to our product candidates, or one of our future product candidates, the defendant could counterclaim that our 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 be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. 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 also raise similar claims before the USPTO or an equivalent foreign body, even outside the context of litigation. Potential proceedings 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 patents in such a way that they no longer cover our technology or any product candidates that we may develop. 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 and the patent examiner were unaware during prosecution. If a defendant 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 the applicable product candidates or technology covered by the patent rendered invalid or unenforceable.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be materially harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Some of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management attention and other resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, or in-license needed technology or other product candidates. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could negatively impact the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the pharmaceutical industry.

We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and their manufacture and our other technology, including re-examination, interference, post-grant review, *inter partes* review or derivation proceedings before the USPTO or an equivalent foreign body. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit.

Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that third-party patents asserted against us are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any of our product candidates and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of a U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of a U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, and we are unsuccessful in demonstrating that these rights are invalid or unenforceable, we could be required to obtain a license from such a third party in order to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing product candidate or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

Many of our employees were previously employed at other biotechnology or pharmaceutical companies, and our consultants and advisors may work for other biotechnology or pharmaceutical companies in addition to us. 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 of these individuals' former or concurrent employers or clients. We may also be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants and advisors, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or 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 prosecuting or defending against these claims, litigation could result in substantial costs, delay development of our product candidates and be a distraction to management.

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, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes that arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning this intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, 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. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

We rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information (including unpatented know-how associated with Warp Drive Bio, Inc.) and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect these 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, 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. We cannot guarantee that we have entered into these agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary information will be effective.

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. 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 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. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor or other third party, our competitive position would be materially and adversely harmed.

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 and unregistered trademarks and trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on 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 collaborators or customers in our markets of interest. At times, competitors 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 claims brought by owners of other 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. We may license our trademarks and trade names to third parties, such as distributors or licensees. Although these license agreements may provide conditions and guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by these third parties may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to our current or future product candidates or utilize similar technology but that are not covered by the claims of our patents or the patents that we license or may own in the future;
- we, or our current or future collaborators might not have been the first to make the inventions covered by an issued patent or pending patent application that we license or may own in the future;
- we or our current or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;

- generative AI technologies are a relatively novel development with evolving regulatory regimes that may not offer intellectual property protections;
- our pending owned or licensed patent applications or those that we may own or license in the future may not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Risks related to employee matters and managing our growth

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

We are highly dependent on members of our executive team. The loss of the services of any of them may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are "at-will" employees. We currently do not have "key person" insurance on any of our employees. The loss of the services of one or more of our key personnel might impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, is critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for skilled individuals. In addition, failure to succeed in preclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or the loss of services of certain executives, key employees, consultants or advisors may impede the progress of our research, development and commercialization objectives.

We will need to increase the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2024, we had 534 full-time employees, including 423 employees engaged in research and development. As our development and commercialization plans and strategies develop, and as we operate as a public company, we expect to need additional managerial, research and development, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to advance development of and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of marketing approval, clinical management and manufacturing. The services of these independent organizations, advisors and consultants may not continue to be available to us on a timely basis when needed, on economically reasonable terms, or at all, and we may be unable to find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by

consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of any current or future product candidates or otherwise advance our business.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize any of our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We currently have a limited commercial organization. If we are unable to establish sufficient sales and marketing capabilities on our own or through third parties, we may not be able to market and sell any products effectively, if approved, or generate product revenue.

We currently have a limited commercial organization. In order to commercialize any product, if approved, in the United States and foreign jurisdictions, we must build our marketing, sales, distribution, market access, analytics, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In advance of any of our product candidates receiving regulatory approval, we expect to establish a sales organization with technical expertise as well as supporting distribution capabilities to commercialize each such product candidate, which will be expensive and time-consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates.

We have in the past engaged and may in the future engage in strategic transactions; these transactions could affect our liquidity, dilute our existing stockholders, increase our expenses and present significant challenges in focus and energy to our management or prove not to be successful.

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. For example, in October 2018, we acquired all of the outstanding shares of Warp Drive Bio, Inc., which became our direct wholly owned subsidiary, and in November 2023, we completed the EQRx Acquisition.

Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could 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 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 of the acquisition.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could negatively impact our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

We or the third parties upon whom we depend are subject to risk from earthquakes, outbreak of disease, other natural disasters and catastrophic events and may be subject to disruption as a result of war, terrorism, political unrest and other causes.

Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes, wildfires and flooding. We do not carry earthquake insurance. Earthquakes, wildfires or other natural disasters could severely disrupt our operations, and negatively impact our business.

A significant natural disaster, power outage, or other catastrophic event, such as telecommunications failure, cyberattack, war, terrorist attack, sabotage, geopolitical event, pandemic, or other public health crisis or other catastrophic occurrence that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, may make it difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could negatively impact our business.

Furthermore, escalation of geopolitical tensions, including as a result of the ongoing war between Russia and Ukraine or escalation of conflicts in the Middle East, could impact our current or planned clinical operations and our business partners and suppliers, which could adversely affect our business, partners, suppliers or the economy as a whole. The extent and duration of the military action, sanctions and resulting market disruptions could be significant and have substantial impact on the global economy and our business for an unknown period of time, including limiting our ability to include European or Middle Eastern sites as clinical trial locations in the future, as a result of which we may have to delay, reduce the scope of or suspend one or more of our clinical trials.

Despite any precautions we may take, the occurrence of a natural disaster or other unanticipated problems could result in lengthy interruptions to our business or disruptions in our activities or the activities of our partners, suppliers or the economy as a whole. All of the aforementioned risks may be further increased if our disaster recovery plans prove to be inadequate.

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

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

Risks related to our common stock and warrants

The price of our common stock is volatile and fluctuates substantially, which could result in substantial losses for investors.

Our stock price is highly volatile. The stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies.

The market price for our common stock may be influenced by many factors, including:

- our research and development efforts and our ability to discover and develop product candidates;

- results of our clinical trials and preclinical studies or those of our competitors;
- the success of competitive products or technologies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license product candidates or companion diagnostics;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions.

In addition, stock markets with respect to public companies, particularly companies in the biotechnology industry, have experienced significant price and volume fluctuations that have affected and continue to affect, the stock prices of these companies. Stock prices of many companies, including biotechnology companies, have fluctuated in a manner often unrelated to the operating performance of those companies. In the past, companies that have experienced volatility in the trading price of their securities have been subject to securities class action litigation.

An active and liquid market for our common stock may not be sustained.

Our common stock is currently listed on the Nasdaq Global Select Market under the symbol "RVMD". The price for our common stock may vary, and an active and liquid market in our common stock may not be sustained. The lack of an active market may impair the value of your shares, your ability to sell your shares at the time you wish to sell them and the prices that you may obtain for your shares. An inactive market may also impair our ability to raise capital by selling our common stock and our ability to acquire other companies, products or technologies by using our common stock as consideration.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, stockholders are not likely to receive any dividends on their common stock for the foreseeable future. Since we do not intend to pay dividends, stockholders' ability to receive a return on their investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline.

As of December 31, 2024, 31.7 million shares of common stock were subject to outstanding options, warrants or restricted stock units and were eligible, or expected to become eligible, for sale in the public market to the extent permitted by the provisions of various vesting schedules, lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

There is no guarantee that our public and private warrants will ever be in the money, and they may expire worthless.

We have public and private warrants that were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and EQRx (the Warrant Agreement). Following the EQRx Acquisition, these warrants became exercisable for shares of our common stock, and we appointed Equiniti Trust Company, LLC as the warrant agent. These warrants entitle registered holders to purchase 0.1112 shares of our common stock at an exercise price of $11.50 per such fractional

share of common stock. There is no guarantee that the warrants will ever be in the money prior to their expiration, and as such, the warrants could expire worthless.

We may amend the terms of our public and private warrants in a manner that may be adverse to holders with the approval by the holders of at least 50% of the then-outstanding warrants. As a result, the exercise price of a holder's warrants could be increased, the exercise period could be shortened and the number of shares of our common stock purchasable upon exercise of a warrant could be decreased, all without the approval of that warrant holder.

The Warrant Agreement provides that the terms of our public and private warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval by the holders of at least 50% of the then-outstanding warrants to make any change that adversely affects the interests of the registered holders. Accordingly, we may only amend the terms of these warrants in a manner adverse to a holder if holders of at least 50% of the then-outstanding warrants approve of the amendment, including to, among other things, increase the exercise price of the warrants, convert the warrants into cash or stock, shorten the exercise period or decrease the number of shares of common stock purchasable upon exercise of a warrant.

We may redeem unexpired public and private warrants prior to their exercise at a time that is disadvantageous to warrant holders, thereby making their warrants worthless.

We have the ability to redeem our outstanding public warrants at any time prior to their expiration (A) at a price of $0.01 per public warrant; provided that the last reported sales price of our common stock equals or exceeds $161.87 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to the date on which we give notice of such redemption to the public warrant holders and provided certain other conditions are met, and (B) at a price of $0.10 per public warrant; provided that (i) holders will be able to exercise their public warrants on a cashless basis prior to redemption and receive that number of shares determined by reference to an agreed table based on the redemption date and the "fair market value" of the common stock, (ii) if the last reported sales price of Common Stock equals or exceeds $89.93 per share (as adjusted for adjustments to the number of shares issuable upon exercise or the exercise price of a public warrant as described in the "Description of Securities" filed as Exhibit 4.3 to this Annual Report on Form 10-K under the heading "Public warrants — Anti-dilution Adjustments") for any 20 trading days within the 30-trading day period ending three trading days before we send the notice of redemption to the public warrant holders, (iii) if the closing price of our common stock for any 20 trading days within a 30-trading day period ending three trading days before we send the notice of redemption to the public warrant holders is less than $161.87 per share (as adjusted), the private warrants must also be concurrently called for redemption on the same terms as the outstanding public warrants and (iv) provided certain other conditions are met. A redemption in accordance with (B) above may result in public warrant holders having to exercise the public warrants at a time when they are out-of-the-money or receive nominal consideration from us for them.

The terms of the private warrants are substantially the same as the public warrants; provided, that, except as described above in the discussion of the redemption of public warrants when the price per share of our common stock equals or exceeds $89.93, the private warrants are exercisable on a cashless basis and are non-redeemable for cash so long as they are held by the initial purchasers or their permitted transferees. If the private warrants are held by someone other than the initial purchasers or their permitted transferees, the private warrants are redeemable by us and exercisable by such holders on the same basis as the public warrants. Please see Exhibit 4.3 "Description of Securities — Warrants — Public Warrants" filed with this Annual Report on Form 10-K for additional information.

If and when these warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding public and private warrants could force the warrant holders: (i) to exercise their warrants and pay the exercise price therefor at a time when it may be disadvantageous for them to do so; (ii) to sell their warrants at the then-current market price when they might otherwise wish to hold their warrants; or (iii) to accept the nominal redemption price which, at the time the outstanding warrants are called for redemption, is likely to be substantially less than the market value of their warrants.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes has been limited by "ownership changes" and may be further limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), and corresponding provisions of state law, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past, and we may experience ownership changes in the future as a result of our public offerings or other changes in our stock ownership (some of which are not in our control). Use of our federal and state net

operating loss carryforwards has been limited as a result of ownership changes and could be further limited if we experience additional ownership changes.

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 changes in control or changes in our management without the consent of our board of directors. These provisions include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to appoint a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by our chief executive officer or president or by our board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case, to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;

- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we are not obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaws to reduce our indemnification obligations to our directors, officers, employees and agents.

Our amended and restated certificate of incorporation and amended and restated bylaws provide for an exclusive forum in the Court of Chancery of the State of Delaware for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any state law derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, any action to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended (the Exchange Act) or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause or causes of action under the Securities Act. Such provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint and any other professional or entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Nothing in our amended and restated certificate of incorporation or amended and restated bylaws precludes stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive-forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition, results of operations and prospects.

General risk factors

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

To date, we have primarily financed our operations through the sale or issuance of preferred stock and common stock and upfront payments and research and development cost reimbursement received in connection with our prior collaboration with Sanofi and the EQRx Acquisition. We will be required to seek additional funding in the future to achieve our goals and may do so through a combination of public or private equity offerings, debt financings, credit or loan facilities, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional capital through marketing and distribution

arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional funds by issuing equity securities, our stockholders may suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. For example, the EQRx Acquisition, an all-stock transaction pursuant to which we issued shares of our common stock according to a blended formula, resulted in substantial dilution to our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities would receive any distribution of our corporate assets. Attempting to secure additional financing may also divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

Litigation or other legal proceedings, including proceedings related to intellectual property and securities class action lawsuits and derivative lawsuits, could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings, may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. There is considerable intellectual property litigation in the pharmaceutical industry. Additionally, securities class action lawsuits and derivative lawsuits are often brought against public companies that have entered into merger agreements or as a result of stock price volatility. 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 result in substantial costs and monetary damages and thus 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. As noted above, 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our product candidates, if approved. See the description of certain current legal proceedings in "Legal Proceedings" contained in Item 3 of this Annual Report on Form 10-K.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, Trade Laws), prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

We may be adversely affected by events in the global economy and events adversely affecting the financial services industry.

We may be adversely affected by general conditions in the global economy and in the global financial markets, including the current inflationary environment. Increased inflation may result in decreased demand for our products (if approved), increased operating costs (including our labor costs), reduced liquidity and limitations on our ability to access credit or otherwise raise debt and equity capital. In addition, the U.S. Federal Reserve has raised, and may again in the future raise, interest rates in response to inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, could have the effect of further increasing economic uncertainty and heightening these risks.

Adverse developments that affect financial institutions or concerns or rumors about these events have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the U.S. Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, other institutions have been and may continue to be swept into receivership. Uncertainty may remain over liquidity concerns in the

broader financial services industry, and there may be unpredictable impacts to our business and our industry. We cannot anticipate all the ways in which the global financial market conditions could adversely impact our business in the future.

Although we assess our banking relationships as we believe necessary or appropriate, our access to deposits or other financial assets on a timely basis or in adequate amounts could be significantly impaired by factors that affect the financial institutions with which we have banking relationships or the financial markets or financial services industry generally. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry.

We maintain our cash at financial institutions, in balances that may exceed federally insured limits.

We maintain the majority of our cash and cash equivalents in accounts at banking institutions in the United States that we believe are of high quality. Cash held in these accounts may exceed the FDIC insurance limits. If these banking institutions were to fail, we could lose all or a portion of amounts held in excess of these insurance limitations. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all.

We incur significantly increased costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley), which could result in sanctions or other penalties that would harm our business.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act, and regulations regarding corporate governance practices. The listing requirements of the Nasdaq Global Select Market and the rules of the SEC require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel devote a substantial amount of time to comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms. 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.

Our current shares outstanding and resulting market valuation do not reflect shares of our common stock issuable upon the exercise of warrants that are exercisable at the discretion of the holders of such warrants. If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We have issued in the past, and may from time to time issue, additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. For example, in August 2024, we entered into a sales agreement with TD Securities (USA) LLC (TD Cowen), to sell shares of our common stock, from time to time, with aggregate gross proceeds of up to $500 million, through an at-the-market equity offering program (the 2024 ATM) under which TD Cowen agreed to act as our sales agent. During the year ended December 31, 2024, we sold an aggregate of 1,147,893 shares of common stock under the 2024 ATM, resulting in gross proceeds of $60.4 million. In November 2023, we completed the EQRx Acquisition, which was an all-stock transaction pursuant to which we (i) issued shares of our common stock according to a blended formula, resulting in substantial dilution to our stockholders, and (ii) assumed public and private warrants to purchase shares of our common stock. Additionally, in December 2024, we completed an underwritten public offering that included the sale of pre-funded warrants to purchase 2,173,917 shares of our common stock. Until exercised, the shares issuable upon the exercise of the warrants are not included in the number of our outstanding shares of common stock. If we issue common stock or securities convertible into common stock in the future, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

If securities analysts do not continue to publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. If few analysts publish research or reports about us, the trading price of our stock would likely decrease. If one or more of the analysts covering our business downgrades their evaluations of our stock, the price of our stock could decline. If one or more of these analysts ceases to cover our stock, we could lose visibility in the market for our stock, which, in turn, could cause our stock price to decline.

If we fail to maintain proper and effective internal controls over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

As a public company, we are subject to Section 404 of Sarbanes-Oxley and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting.

In order to provide the reports required by these rules we must conduct reviews and testing of our internal controls. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis, and our financial statements may be materially misstated. Further, failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company, we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend on third-party vendors to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares and public warrants from the Nasdaq Global Select Market or other adverse consequences.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity and availability of our critical systems and information.

Our cybersecurity program is designed to align with industry standards and best practices for similarly situated companies in our industry and at our stage of development, and includes benchmarking against standards such as the National Institute of Standards and Technology Cybersecurity Framework (the NIST CSF). This does not imply that we meet any particular technical standards, specifications or requirements, only that we use the NIST CSF as a guide to help us identify, assess and manage cybersecurity risks relevant to our business. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through periodic vulnerability scans, penetration tests and threat intelligence feeds. We use various tools and methodologies to manage cybersecurity risk that are tested on a periodic cadence.

Our cybersecurity risk management program is integrated into our overall risk management program, and shares common methodologies, reporting channels and governance processes that apply across the risk management program to other legal, compliance, strategic, operational and financial risk areas.

Key elements of our cybersecurity risk management program include but are not limited to the following:

- risk assessments designed to help identify material risks from cybersecurity threats to our critical systems and information;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls and (3) our response to cybersecurity incidents;

- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security processes;
- cybersecurity awareness training that is provided to our employees and contractors, including those who are involved in incident response;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- assessment of cybersecurity risks posed by third parties, including current and potential collaborators, service providers, suppliers, vendors and other contractual counterparties, in each case, to the extent they have access to our critical systems or information.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. We face risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information, see the section titled "Risk Factor— Risks related to product development and regulatory process— Our business and operations, or those of our CROs or other third parties, may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity, which could materially affect our business, results of operations and financial condition.".

Cybersecurity Governance

Our board of directors considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee oversight of cybersecurity risks, including oversight of management's implementation of our cybersecurity risk management program.

The Audit Committee receives scheduled annual reports from management on our cybersecurity risks, our cybersecurity risk management program and other cybersecurity-related educational topics. In addition, management updates the Audit Committee as necessary, regarding other cybersecurity incidents, including any material cybersecurity incidents.

The Audit Committee reports to the full Board regarding its activities, including those related to cybersecurity. Our full board of directors also receives briefings from management where it deems appropriate regarding cybersecurity.

Our management team—including our Chief Information Officer and our Vice President, Information Security, Risk and Compliance—is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our Chief Information Officer and our Vice President, Information Security, Risk and Compliance have more than 40 years of combined experience in the field of IT.

Our management team takes steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal information security personnel; threat intelligence and other information obtained from government, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in our IT environment.

Item 2. Properties.

Our corporate headquarters is located in Redwood City, California, where we lease and occupy approximately 233,065 square feet of office and laboratory space. The term of our Redwood City lease expires in December 2035.

Our lease of approximately 22,000 square feet of office and laboratory space in Cambridge, Massachusetts, which was subleased to Casma Therapeutics, Inc. expired in February 2023.

We believe our existing facilities are sufficient for our needs for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we are and may become involved in litigation or other legal proceedings arising from the normal course of business activities. Defending such proceedings is costly and can impose a significant burden on management and employees. The results of any current or future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

On December 9, 2024, *Nemeth v. Casdin, et al.*, Case No. 2024-1268-KSJM (Del. Ch.), was filed in the Court of Chancery of the State of Delaware (the Complaint) arising from CM Life Sciences III., Inc.'s (CMLS III) December 17, 2021 merger with EQRx., Inc. (Legacy EQRx) (the Merger). The Complaint was filed by former stockholders of CMLS III and brings claims for breach of fiduciary duty and unjust enrichment against members of CMLS III's board of directors, CMLS III's officers, and CMLS III's sponsor in connection with the Merger. The Complaint also brings claims for aiding and abetting breaches of fiduciary duties against certain investment firms involved with the merger process, the Company, solely as successor-in-interest to EQRx, and Legacy EQRx's former Executive Chairman and CEO, Alexis Borisy, who is also on our board of directors. Defendants' response to the Complaint is due on February 28, 2025.

At this juncture, we do not believe this action will have a material adverse impact on our operations or financial position. Although we believe a loss relating to the Complaint is reasonably possible, given the early stage of the case (i.e., before any motion to dismiss rulings or discovery), we cannot make an estimate regarding the range of loss. We intend to defend vigorously against the Complaint.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market price of common stock

Our common stock and public warrants are listed on the Nasdaq Global Select Market under the symbols "RVMD" and "RVMDW", respectively. Prior to February 13, 2020, there was no public trading market for our common stock.

As of February 21, 2025, there were 64 holders of record of our common stock and 5 holders of record of our public warrants. We believe the actual number of holders of our common stock is greater than the number of record holders included herein as this number does not include holders whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

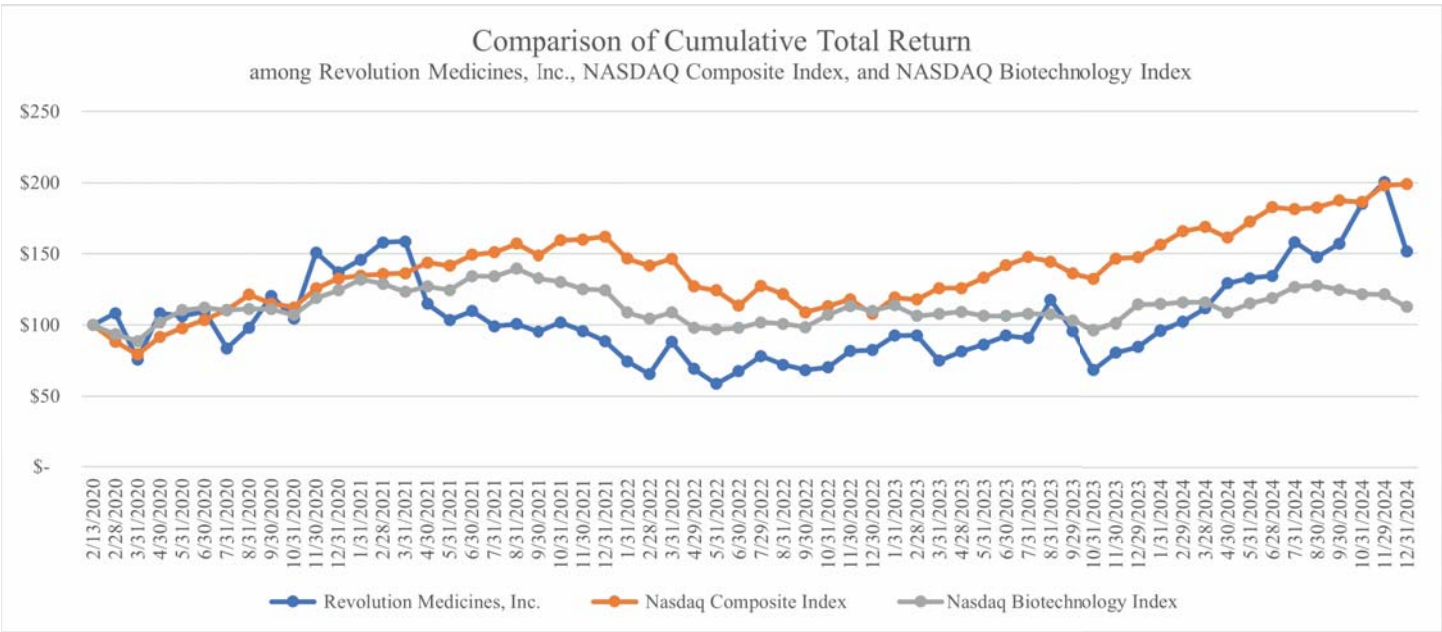
Dividend policy

We 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.

Stock performance graph

This graph is not "soliciting material" or deemed "filed" with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to liabilities under that Section, and shall not be deemed incorporated by reference into any filing of Revolution Medicines, Inc. under the Securities Act of 1933, as amended (the Securities Act), whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph compares the cumulative total return to stockholder return on our common stock relative to the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. An investment of $100 is assumed to have been made in our common stock and each index on February 13, 2020 (the first day of trading of our common stock) and its relative performance is tracked through December 31, 2024. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends; however, no dividends have been declared on our common stock to date. The stockholder returns shown on the graph below are based on historical results and are not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



Recent sales of unregistered securities

None.

Issuer Purchases of Equity Securities

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 in conjunction with the consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations 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 on Form 10-K, our actual results could differ materially from the results described or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage precision oncology company developing novel targeted therapies for RAS-addicted cancers. We possess sophisticated structure-based drug discovery capabilities built upon deep chemical biology and cancer pharmacology know-how and innovative, proprietary technologies that enable the creation of small molecules tailored to unconventional binding sites. Guided by our understanding of genetic drivers and adaptive resistance mechanisms in cancer, we deploy precision medicine approaches to inform innovative monotherapy and combination regimens.

Our research and development pipeline comprises RAS(ON) inhibitors that bind directly to RAS variants, which we refer to as RAS(ON) Inhibitors, and RAS companion inhibitors that target key nodes in the RAS pathway or associated pathways. Our RAS(ON) Inhibitors are designed to be used as monotherapy, in combination with other RAS(ON) Inhibitors and/or in combination with RAS companion inhibitors or other therapeutic agents.

RAS(ON) Inhibitors

Our RAS(ON) Inhibitors are based on our proprietary tri-complex technology platform, which enables a highly differentiated approach to inhibiting the active, GTP-bound form of RAS, which we refer to as RAS(ON). We are developing a portfolio of compounds that we believe were the first RAS(ON) Inhibitors to use this mechanism of action. We believe that direct inhibitors of RAS(ON) suppress cell growth and survival and are less susceptible to adaptive resistance mechanisms recognized for RAS(OFF) inhibitors.

We are evaluating our RAS(ON) Inhibitors alone and in combination with other drugs and investigational drug candidates, particularly in-pathway agents. We believe tailored RAS(ON) Inhibitors will be useful to serve the diverse landscape of RAS-addicted cancers optimally. We believe that in some cases, patients may experience maximal clinical benefit from the broad activity of our RAS(ON) multi-selective inhibitor, daraxonrasib (RMC-6236), if approved. In others, we believe treatment with a RAS(ON) mutant-selective inhibitor may be optimal. We further believe that in some cases, it could be beneficial to combine daraxonrasib with a RAS(ON) mutant-selective inhibitor, with daraxonrasib functioning as the backbone of these RAS(ON) Inhibitor doublets. In addition, we believe that in some cases, combination of our RAS(ON) Inhibitors with standard of care therapies, including immunotherapies, may be optimal.

We are advancing a deep pipeline of RAS(ON) Inhibitors, including daraxonrasib (RMC-6236), our RAS(ON) multi-selective inhibitor; elironrasib (RMC-6291), our G12C-selective inhibitor; and zoldonrasib (RMC-9805), our G12D-selective inhibitor. Together, we consider these three clinical-stage candidates as the first wave of RAS(ON) inhibitors that we are advancing through clinical development. We also currently plan to advance RMC-5127 (G12V) into clinical development. In addition, we have other preclinical-stage RAS(ON) inhibitor clinical development opportunities, including the RAS(ON) mutant-selective inhibitors RMC-0708 (Q61H) and RMC-8839 (G13C).

Daraxonrasib (RMC-6236)

Daraxonrasib (RMC-6236), our RAS(ON) multi-selective inhibitor, is designed as an oral, RAS-selective tri-complex inhibitor of multiple RAS(ON) variants containing cancer driver mutations at all three of the major RAS mutation hotspot positions (G12, G13 and Q61). Daraxonrasib inhibits all three major RAS isoforms, suppressing the mutant cancer driver and cooperating wild-type RAS proteins.

A global, randomized Phase 3 registrational trial of daraxonrasib in the second-line (2L) treatment of patients with metastatic pancreatic ductal adenocarcinoma (PDAC), which we call the RASolute 302 study, is ongoing. In the RASolute 302 study, we are randomizing patients in a 1:1 ratio to receive either daraxonrasib at a dose of 300 mg daily or the investigator's choice of chemotherapy. The RASolute 302 study has a nested trial design allowing for a hierarchical sequence of statistical analysis, with patients with tumors harboring RAS G12X mutations serving as the core population which will be tested first and all enrolled patients serving as the secondary population. We believe this nested design and hierarchical testing increases the probability of trial success based on the core population while creating an opportunity to gain approval for a broader population. Patients in the RASolute 302 study will be evaluated for the dual primary endpoints of progression-free survival (PFS) and overall survival (OS) in the core

population, with secondary endpoints including PFS and OS in the secondary population and objective response rate (ORR) and quality of life measures. We currently expect to substantially complete enrollment of the RASolute 302 study in 2025, to enable an expected clinical readout in 2026.

Having finalized the study protocol, we are now activating sites for a global, randomized Phase 3 registrational trial comparing daraxonrasib versus docetaxel in patients with locally advanced or metastatic RAS-mutated non-small cell lung cancer (NSCLC) who have been treated with immunotherapy and platinum-containing chemotherapy, which we call the RASolve 301 study. In the RASolve 301 study, we are randomizing patients in a 1:1 ratio to receive either daraxonrasib or docetaxel. The RASolve 301 study has a nested trial design allowing for a hierarchical sequence of statistical analysis, with patients with tumors harboring RAS G12X (other than G12C) mutations serving as the core population which will be tested first, and all enrolled patients serving as the secondary population. We believe this nested design and hierarchical testing increases the probability of trial success based on the core population while creating an opportunity to gain approval for a broader population. Patients in the RASolve 301 study will be evaluated for the dual primary endpoints of PFS and OS in the core population, with secondary endpoints including PFS and OS in the secondary population and ORR and quality of life measures.

We currently expect to initiate a global, randomized Phase 3 daraxonrasib monotherapy study in patients with first-line (1L) metastatic PDAC in the second half of 2025. We also currently expect to initiate a global, randomized Phase 3 monotherapy study of daraxonrasib as adjuvant treatment for patients with resectable PDAC in the second half of 2025.

On December 2, 2024 we reported updated clinical safety, tolerability, and activity data for daraxonrasib from our first-in-human monotherapy study of daraxonrasib, which we refer to as the RMC-6236-001 study, in patients with previously treated RAS-mutant PDAC as of a data cutoff date of July 23, 2024. We believe these data showed that daraxonrasib was generally well tolerated and demonstrated encouraging antitumor activity that supported our initiation of the RASolute 302 study.

Also on December 2, 2024, we reported clinical safety and tolerability data as of a September 30, 2024 data cutoff date for daraxonrasib from the RMC-6236-001 study in patients with NSCLC with tumors harboring RAS mutations. We also reported clinical activity data as of a September 30, 2024 data cutoff date for daraxonrasib from the RMC-6236-001 study in patients with NSCLC with tumors harboring RAS G12X mutations who had received one or two prior lines of therapy which must have included prior immunotherapy and platinum chemotherapy administered either concurrently or sequentially, but not docetaxel, a study population matching the planned RASolve 301 enrollees. We believe these data showed that daraxonrasib was generally well tolerated and demonstrated encouraging antitumor activity that supported our initiation of the RASolve 301 study.

Based on our observations from the RMC-6236-001 study and our preclinical observations, we believe there is a potential opportunity to evaluate daraxonrasib combinations in earlier lines of therapy in multiple tumor types, and we are currently evaluating several exploratory combination regimens that include daraxonrasib in order to assess the potential for development in these settings. These combinations include daraxonrasib with pembrolizumab, daraxonrasib with elironrasib, daraxonrasib with zoldonrasib and daraxonrasib with standard of care chemotherapy agents.

On December 2, 2024, we disclosed initial clinical safety and tolerability data as of a data cutoff date of October 28, 2024 from our clinical study of the combination of daraxonrasib with pembrolizumab, which we believe showed the combination was generally well tolerated with limited hepatotoxicity.

Also on December 2, 2024, we disclosed initial clinical safety, tolerability and activity data as of a data cutoff date of October 28, 2024 from our clinical study of the combination of daraxonrasib with elironrasib, which we believe showed the combination was generally well tolerated and provide initial proof-of-mechanism for a RAS(ON) inhibitor doublet in patients with colorectal cancer (CRC) who were previously treated with KRAS(OFF) G12C inhibitors. We believe these preliminary data observations support continued development of RAS(ON) inhibitor doublets in a broad range of tumor types and earlier lines of therapy, including 1L patients with NSCLC carrying RAS G12C tumors.

In April 2024, at the American Association for Cancer Research (AACR) Annual Meeting 2024, we reported individual case studies from the RMC-6236-001 study that showed examples of objective responses to daraxonrasib in patients with tumor types beyond PDAC or NSCLC, specifically patients with melanoma and with CRC.

Elironrasib (RMC-6291)

Elironrasib (RMC-6291) is designed as a RAS(ON) oral tri-complex G12C-selective inhibitor. It is designed to exhibit subnanomolar potency for suppressing RAS pathway signaling and growth of RAS G12C-bearing cancer cells and is engineered to be highly selective for RAS G12C over wild-type RAS and other cellular targets. Elironrasib is designed to be differentiated from first-

generation KRAS(OFF) G12C inhibitors, which sequester the KRAS(OFF) G12C form, by its mechanism of directly inhibiting the RAS(ON) G12C form.

On October 13, 2023, we reported interim preliminary safety and anti-tumor data from our ongoing first-in-human study of elironrasib, which we refer to as the RMC-6291-001 study, as of an October 5, 2023 data cut-off date, which we believe provide preliminary evidence of clinically meaningful differentiation of elironrasib from KRAS(OFF) G12C inhibitors.

We are evaluating several exploratory combination regimens that include elironrasib in order to assess the potential for development in earlier lines of therapy. These combinations include elironrasib with pembrolizumab and, as discussed in the "*Daraxonrasib (RMC-6236*)" section above, elironrasib with daraxonrasib. We are also planning a combination study of elironrasib with both daraxonrasib and pembrolizumab.

On December 2, 2024, we disclosed initial clinical safety, tolerability and activity data for the combination of daraxonrasib with elironrasib, as discussed in the "*Daraxonrasib (RMC-6236*)" section above.

Also on December 2, 2024, we disclosed clinical safety and tolerability data as of a data cutoff date of October 28, 2024 for the combination of elironrasib with pembrolizumab, which we believe showed the combination was generally well tolerated with limited hepatotoxicity.

Zoldonrasib (RMC-9805)

Zoldonrasib (RMC-9805) is designed as a RAS(ON) oral tri-complex G12D-selective inhibitor. It is designed to exhibit low nanomolar potency for suppressing RAS pathway signaling and growth of RAS G12D-bearing cancer cells and is engineered to covalently inactivate RAS G12D irreversibly.

On October 25, 2024, we reported preliminary clinical safety, tolerability and activity data as of a data cutoff date of September 2, 2024 from our first-in-human monotherapy study of zoldonrasib, which we refer to as the RMC-9805-001 study in patients with previously treated solid tumors harboring KRAS G12D mutations.

We believe that these data support our ongoing development of zoldonrasib as a single agent and in combination with other therapies, including with daraxonrasib. An exploratory combination study of zoldonrasib with daraxonrasib is ongoing. We currently expect to disclose additional zoldonrasib clinical safety and antitumor activity data in the second quarter of 2025.

We currently expect to initiate one or more pivotal combination studies in 2026 that incorporate either zoldonrasib or elironrasib and currently expect to share clinical data supporting these plans in the second or third quarter of 2025.

RMC-5127

RMC-5127 is designed as a RAS(ON) oral G12V-selective inhibitor. It is designed to exhibit picomolar potency for suppressing RAS pathway signaling and growth of RAS G12V-bearing cancer cells and is engineered for selective inhibition of RAS G12V over other RAS isoforms via non-covalent binding interactions. We currently expect to advance RMC-5127 to a clinic-ready stage in 2025 and to initiate a first-in-human dose escalation clinical trial of RMC-5127 in 2026.

RMC-0708

RMC-0708 is designed as a RAS(ON) oral Q61H-selective inhibitor. It is designed to exhibit picomolar potency for suppressing RAS pathway signaling and growth of RAS Q61H-bearing cancer cells and is engineered for selective inhibition of RAS Q61H over other RAS isoforms via non-covalent binding interactions. Clinical development of RMC-0708 is subject to our continuing assessment of our portfolio priorities.

RMC-8839

RMC-8839 is designed as a RAS(ON) oral G13C-selective inhibitor. It is designed to exhibit picomolar potency for suppressing RAS pathway signaling and growth of KRAS G13C-bearing cancer cells and is engineered to covalently inactivate KRAS G13C for irreversible inhibition. Clinical development of RMC-8839 is subject to our continuing assessment of our portfolio priorities.

Other Development Opportunities

We have developed RAS companion inhibitors that are designed to suppress cooperating targets and pathways that sustain RAS-addicted cancers. These compounds include RMC-4630, which is designed as a potent and selective inhibitor of SHP2; RMC-5552,

which is designed as a selective inhibitor of mTORC1 signaling in tumors; and RMC-5845, which is designed to target SOS1 a protein that plays a key role in converting RAS(OFF) to RAS(ON) in cells. Additional clinical development of our RAS companion inhibitors is subject to our continuing assessment of our portfolio priorities.

We are also developing preclinical next-generation programs that are designed to sustain our innovation platform beyond our current development-stage assets.

Acquisition of EQRx, Inc.

On November 9, 2023 (the Closing Date), we completed the acquisition of EQRx, Inc. (the EQRx Acquisition), pursuant to the Agreement and Plan of Merger, dated as of July 31, 2023 (the Merger Agreement). Pursuant to the Merger Agreement, EQRx, LLC survived as our wholly owned subsidiary.

On the Closing Date, each share of EQRx, Inc. common stock issued and outstanding immediately prior to the completion of the EQRx Acquisition was converted into the right to receive 0.1112 shares of our common stock. Outstanding stock options, restricted stock units and restricted stock awards of EQRx, Inc. were also converted into our common stock subject to the terms of the Merger Agreement. We issued 54.8 million shares of our common stock and paid $4.0 million in taxes to satisfy statutory income tax withholding obligations in conjunction with the EQRx Acquisition.

As a result of the EQRx Acquisition, we acquired $1.1 billion in net cash, cash equivalents and marketable securities after deducting estimated EQRx wind-down and transaction costs.

For additional information regarding the terms of the EQRx Acquisition, see "Note 3. Acquisition" in the "Notes to Consolidated Financial Statements" contained in Part II, Item 8 of this Annual Report on Form 10-K.

Aethon Collaboration

In March 2024, we entered into a collaboration agreement with Aethon Therapeutics, Inc. (Aethon) pursuant to which Aethon is conducting research related to use of novel bispecific antibodies to mount an immune attack directed at the cancer cells targeted by our RAS(ON) Inhibitors (the Aethon Collaboration Agreement). Pursuant to the Aethon Collaboration Agreement, we agreed to reimburse Aethon for preclinical activities, and we have an option to conduct any clinical or commercial development that may arise from the collaboration.

Financial Operations Overview

Collaboration revenue

Collaboration revenue consisted of revenue under the Sanofi Agreement for our SHP2 program. We received a $50.0 million upfront payment from Sanofi in July 2018 and received reimbursement for research and development services. The Sanofi Agreement was terminated in June 2023.

For further information on our revenue recognition policies, see "Note 2. Summary of significant accounting policies" in the "Notes to Consolidated Financial Statements" contained in Part II, Item 8 of this Annual Report on Form 10-K.

Research and development expenses

We substantially rely on third parties to conduct our preclinical studies, clinical trials and manufacturing. We estimate research and development expenses based on estimates of services performed, and we rely on third party contractors and vendors to provide us with timely and accurate estimates of expenses of services performed to assist us in these estimates. Research and development expenses consist primarily of costs incurred for the development of our product candidates and costs associated with identifying compounds through our discovery platform, which include:

- external costs incurred under agreements with third-party contract organizations, investigative clinical trial sites that conduct research and development activities on our behalf and consultants;
- costs related to the production of preclinical, clinical and pre-launch materials, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of discovery programs, preclinical and clinical trials;
- employee-related expenses, which include salaries, benefits and stock-based compensation; and

- facilities and other expenses, which include allocated expenses for rent and maintenance of facilities, depreciation and amortization expense, information technology and other supplies.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, collaborators and third-party service providers. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and recorded as prepaid assets. The prepaid amounts are then expensed as the related goods are delivered or as services are performed.

We expect our research and development expenses to increase for the foreseeable future as we continue to invest in discovering and developing product candidates and advancing product candidates into later stages of development, which may include conducting larger clinical trials. The process of conducting the necessary research and development and clinical trials to seek regulatory approval for product candidates is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or clinical trials or if and to what extent we will generate revenue from the commercialization and sale of any of our product candidates, if approved.

General and administrative expenses

General and administrative expenses consist primarily of personnel-related costs, consultants and professional services expenses, including legal, audit, accounting and human resources services, insurance, commercial preparation activities, allocated facilities and information technology costs, and other general operating expenses not otherwise classified as research and development expenses. Personnel-related costs consist of salaries, benefits and stock-based compensation. Facilities costs consist of rent, utilities and maintenance of facilities. We expect our general and administrative expenses to increase for the foreseeable future due to anticipated increases in operating and commercial preparation activities, which may result in increases in personnel-related costs associated with increased headcount, other administrative and professional services, and related overhead needed to support these efforts.

Interest income

Interest income primarily consists of interest earned on and accretion of our cash equivalents and marketable securities.

Results of operations

Comparison of the years ended December 31, 2024 and 2023

	Years Ended December 31,		Increase/ (decrease)
	2024	2023	
		(in thousands)	
Revenue:			
Collaboration revenue	$ —	$ 11,580	$ (11,580)
Total revenue	—	11,580	(11,580)
Operating expenses:			
Research and development	592,225	423,144	169,081
General and administrative	97,299	75,621	21,678
Total operating expenses	689,524	498,765	190,759
Loss from operations	(689,524)	(487,185)	(202,339)
Other income (expense), net:			
Interest income	86,883	47,482	39,401
Other expense	(2,528)	(303)	(2,225)
Change in fair value of warrant liability and contingent earn-out shares	4,323	115	4,208
Total other income, net	88,678	47,294	41,384
Loss before income taxes	(600,846)	(439,891)	(160,955)
Benefit from income taxes	753	3,524	(2,771)
Net loss	$ (600,093)	$ (436,367)	$ (163,726)

Collaboration revenue

Collaboration revenue in 2023 consisted of revenue under the Sanofi Agreement, which was terminated in June 2023. Collaboration revenue decreased by $11.6 million, or 100%, during the year ended December 31, 2024 compared to 2023. The decrease in collaboration revenue in 2023 was a result of the termination of the Sanofi Agreement.

Research and development expenses

Our research and development efforts during the year ended December 31, 2024 were focused on our clinical development programs and our preclinical programs. The following table sets forth the components of our research and development expenses for the periods indicated:

	Years Ended December 31,		Increase/ (decrease)
	2024	2023	
	(in thousands)		
Third-party research and development expenses:			
Clinical Development Programs:			
Daraxonrasib (RMC-6236)	$ 168,911	$ 107,947	$ 60,964
Elironrasib (RMC-6291)	55,034	32,593	22,441
Zoldonrasib (RMC-9805)	64,112	40,657	23,455
RAS companion inhibitors	6,955	16,252	(9,297)
Preclinical programs	73,089	65,156	7,933
Total third-party research and development expenses	368,101	262,605	105,496
Salaries and other employee-related expenses	113,475	81,658	31,817
Stock-based compensation expense	50,973	34,126	16,847
Amortization of intangible assets	1,069	1,068	1
Other research and development costs	58,607	43,687	14,920
Total research and development expense	$ 592,225	$ 423,144	$ 169,081

Research and development expenses increased by $169.1 million, or 40%, during the year ended December 31, 2024 compared to 2023. The increase in research and development expenses during the year ended December 31, 2024 was primarily due to a $61.0 million increase in daraxonrasib expenses, primarily attributable to higher clinical trial expenses; a $31.8 million increase in salaries and other employee-related expenses due to increased headcount to support our research and development programs; a $23.5 million increase in zoldonrasib expenses, primarily attributable to higher clinical trial expenses; a $22.4 million increase in elironrasib expenses, primarily attributable to higher clinical trial expenses; a $16.8 million increase in stock-based compensation; a $14.9 million increase in other research and development expenses as a result of higher rent, utilities and information technology expenses associated with increased headcount; and a $7.9 million increase in preclinical research portfolio expenses; partially offset by a $9.3 million decrease in other RAS companion inhibitor program expenses.

General and administrative expenses

General and administrative expenses increased by $21.7 million, or 29%, during the year ended December 31, 2024 compared to 2023. The increase in general and administrative expenses during the year ended December 31, 2024 was primarily due to a $6.7 million increase in pre-commercial development expenses; a $4.5 million increase in salaries and other employee-related expenses due to increased headcount; a $4.5 million increase in facilities and other allocated expenses as a result of higher rent, utilities and information technology expenses associated with increased headcount; a $3.3 million increase in legal and accounting fees; and a $1.2 million increase in insurance and other fees.

Interest income

Interest income increased by $39.4 million for the year ended December 31, 2024, compared to 2023 due to a larger cash, cash equivalents and marketable securities balance and higher interest rates.

Comparison of the years ended December 31, 2023 and 2022

	Years Ended December 31,		Increase/ (decrease)
	2023	2022	
		(in thousands)	
Revenue:			
Collaboration revenue	$ 11,580	$ 35,380	$ (23,800)
Total revenue	11,580	35,380	(23,800)
Operating expenses:			
Research and development	423,144	253,073	170,071
General and administrative	75,621	40,586	35,035
Total operating expenses	498,765	293,659	205,106
Loss from operations	(487,185)	(258,279)	(228,906)
Other income (expense), net:			
Interest income	47,482	9,154	38,328
Interest expense	(303)	—	(303)
Change in fair value of warrant liability and contingent earn-out shares	115	—	115
Total other income (expense), net	47,294	9,154	38,140
Loss before income taxes	(439,891)	(249,125)	(190,766)
Benefit from income taxes	3,524	420	3,104
Net loss	$ (436,367)	$ (248,705)	$ (187,662)

Collaboration revenue

Collaboration revenue consisted of revenue under the Sanofi Agreement, which was terminated in June 2023. Collaboration revenue decreased by $23.8 million, or 67%, during the year ended December 31, 2023 compared to 2022. The decrease in collaboration revenue in 2023 was a result of lower reimbursed expenses from Sanofi.

Research and development expenses

Research and development expenses increased by $170.1 million, or 67%, during the year ended December 31, 2023 compared to 2022. The increase in research and development expenses during the year ended December 31, 2023 was primarily due to a $72.6 million increase in daraxonrasib expenses, primarily attributable to clinical trial and clinical supply manufacturing expenses as daraxonrasib commenced clinical trials at the end of the second quarter of 2022; a $24.1 million increase in salaries and other employee-related expenses due to increased headcount to support our research and development programs; a $17.0 million increase in our preclinical research portfolio expenses; a $16.0 million increase in stock-based compensation including $3.7 million in connection with the EQRx Acquisition; a $15.8 million increase in zoldonrasib expenses, which commenced clinical trials in the third quarter of 2023; a $12.9 million increase in facilities and other allocated expenses as a result of higher rent, utilities and information technology expenses associated with increased headcount; a $12.6 million increase in elironrasib expenses, which commenced clinical trials in the third quarter of 2022; and a $8.2 million increase in employee-related expenses in connection with the EQRx Acquisition; partially offset by a $9.0 million decrease in SHP2 costs.

General and administrative expenses

General and administrative expenses increased by $35.0 million, or 86%, during the year ended December 31, 2023 compared to 2022. The increase in general and administrative expenses during the year ended December 31, 2023 was primarily due to a $14.6 million increase in stock-based compensation expense including $7.5 million in connection with the EQRx Acquisition; a $7.1 million increase in salaries and other employee-related expenses due to increased headcount; a $6.1 million increase in employee-related expenses in connection with the EQRx Acquisition; a $3.2 million increase in facilities and other allocated expenses as a result of higher rent, utilities and information technology expenses associated with increased headcount; a $2.3 million increase in legal and accounting fees; and a $1.6 million increase in pre-commercial development expenses.

Interest income

Interest income increased by $38.3 million for the year ended December 31, 2023, compared to 2022 due to a larger cash, cash equivalents and marketable securities balance and higher interest rates.

Liquidity and Capital Resources

In November 2021, we entered into a sales agreement with Cowen and Company, LLC, an affiliate of TD Securities (USA) LLC (TD Cowen), as amended in March 2024, to sell shares of our common stock, from time to time, with aggregate gross proceeds of up to $250 million, through an at-the-market equity offering program (the 2021 ATM). From November 2021 to August 2024, we sold an aggregate of 6,502,078 shares of our common stock under the 2021 ATM, resulting in gross proceeds to us of $186.0 million. During the year ended December 31, 2024, we sold an aggregate of 1,294,050 shares of common stock under the 2021 ATM, resulting in gross proceeds of $60.8 million. In August 2024, we terminated the 2021 ATM and entered into a new sales agreement with TD Cowen to sell shares of our common stock, from time to time, with aggregate gross proceeds of up to $500 million, through an at-the-market equity offering program (the 2024 ATM). Through December 31, 2024, we have sold an aggregate of 1,147,893 shares of common stock under the 2024 ATM, resulting in gross proceeds of $60.4 million.

In July 2022, we issued 13,225,000 shares of our common stock in an underwritten public offering at a price to the public of $20.00 per share, for net proceeds of $248.1 million, after deducting underwriting discounts and commissions of $15.9 million and offering expenses of $0.5 million.

In March 2023, we issued 15,681,818 shares of our common stock in an underwritten public offering at a price to the public of $22.00 per share, for net proceeds of $323.7 million, after deducting underwriting discounts and commissions of $20.7 million and expenses of $0.6 million.

In November 2023, we completed the EQRx Acquisition and issued 54,786,528 shares of common stock in the transaction in which we received approximately $1.1 billion in net cash, cash equivalents and marketable securities after deducting EQRx wind-down and transition costs.

In December 2024, we issued and sold in an underwritten public offering (i) 16,576,088 shares of our common stock at a price to the public of $46.00 per share and (ii) pre-funded warrants to certain investors to purchase an aggregate of 2,173,917 shares of our common stock at a price of $45.9999 per pre-funded warrant. Each pre-funded warrant will be exercisable from the date of issuance until fully exercised, subject to an ownership limitation. Total net proceeds from the offering were $823.0 million, after deducting underwriting discounts and commissions of $38.8 million and expenses of $0.6 million.

Our operations have been financed primarily by our public offerings of common stock, the EQRx Acquisition and $188.7 million received under the Sanofi Agreement from June 2018 through June 2023 for upfront payments and for research and development cost reimbursement.

As of December 31, 2024, we had $2.3 billion in cash, cash equivalents and marketable securities.

As of December 31, 2024, we had an accumulated deficit of $1.7 billion. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to our product candidates and our pre-clinical research portfolio, and to a lesser extent, general and administrative expenditures. We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we continue to advance our product candidates into later stages of development, which includes conducting larger clinical trials, and increase our efforts of preparing to become a commercial-stage company.

We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our planned operations for at least 12 months following the date of this Annual Report on Form 10-K.

The timing and amount of our future funding requirements depends on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates and programs, and of conducting preclinical studies and clinical trials;
- the cost of manufacturing our current and future product candidates for clinical trials in preparation for marketing approval and in preparation for commercialization;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates if clinical trials are successful;
- the cost of commercialization activities for any of our product candidates, whether alone or in collaboration, including marketing, sales and distribution costs if any product candidate is approved for sale;
- our ability to establish and maintain strategic licenses 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 timing, receipt and amount of sales of, profit share or royalties on, our future products, if any;
- the emergence of competing cancer therapies or other adverse market developments; and
- any plans to acquire or in-license other programs or technologies.

We will require substantial additional financing for our development efforts for our current and future programs and to prepare for their potential commercialization. We do not have any committed external source of funds or other support for these activities, and we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, credit or loan facilities, acquisitions, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we need to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to (i) delay, limit, reduce the scope of or terminate one or more of our preclinical studies, clinical trials, or other research and development activities or eliminate one or more of our development programs altogether; or (ii) delay, limit, reduce the scope of or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize any future approved products, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

Cash Flows

The following table summarizes our consolidated cash flows for the periods indicated:

	Year Ended December 31,		
	2024	2023	2022
		(in thousands)	
Net cash provided by (used in):			
Operating activities	$ (557,436)	$ (350,572)	$ (224,401)
Investing activities	(554,394)	(342,598)	(24,116)
Financing activities	959,413	1,229,200	301,432
Net change in cash and cash equivalents	$ (152,417)	$ 536,030	$ 52,915

Cash used in operating activities

During the year ended December 31, 2024, cash used in operating activities of $557.4 million was attributable to a net loss of $600.1 million, partially offset by $42.3 million in non-cash charges and by a net change of $0.4 million in our operating assets and liabilities. The non-cash charges primarily consisted of stock-based compensation expense of $79.2 million, depreciation and amortization of $7.6 million, amortization of operating lease right-of-use asset of $4.2 million, offset by net amortization of premium on marketable securities of $44.6 million and change in the fair value of warrant liability and contingent earn-out shares of $4.3 million. The change in operating assets and liabilities was primarily due to a $9.7 million increase in prepaid expenses and other current assets, a $5.9 million increase in other noncurrent assets, a $6.5 million decrease in accounts payable, offset by a $22.0 million increase in accrued expenses and other current liabilities primarily related to clinical trial and clinical supply manufacturing expenses and increased personnel related expenses due to increased headcount and a $1.3 million decrease in accounts receivable.

During the year ended December 31, 2023, cash used in operating activities of $350.6 million was attributable to a net loss of $436.4 million, partially offset by $49.0 million in non-cash charges and by a net change of $36.8 million in our operating assets and liabilities. The non-cash charges primarily consisted of stock-based compensation expense of $61.8 million, depreciation and amortization of $6.1 million, amortization of operating lease right-of-use asset of $3.2 million, offset by net amortization of premium on marketable securities of $22.2 million. The change in operating assets and liabilities was primarily due to a $2.6 million increase in prepaid expenses and other current assets, a $4.5 million decrease in deferred revenue associated with the Sanofi Agreement, a $1.5 million decrease in operating lease liability, a $3.9 million decrease in deferred tax liability, a $1.4 million increase in other noncurrent assets, offset by a $32.5 million increase in accounts payable, $14.7 million increase in accrued expenses and other current liabilities primarily related to clinical trial and clinical supply manufacturing expenses and increased personnel related expenses due to increased headcount and a $3.4 million decrease in accounts receivable.

During the year ended December 31, 2022, cash used in operating activities of $224.4 million was attributable to a net loss of $248.7 million and by a net change of $13.5 million in our operating assets and liabilities, partially offset by $37.8 million in non-cash charges. The non-cash charges primarily consisted of stock-based compensation expense of $31.2 million, depreciation and amortization of $5.0 million, amortization of operating lease right-of-use asset of $4.6 million offset by net amortization of premium on marketable securities of $3.1 million. The change in operating assets and liabilities was primarily due to a $3.8 million increase in prepaid expenses and other current assets primarily resulting from the timing of prepayments made for research and development activities, a $14.5 million decrease in deferred revenue associated with the Sanofi Agreement, a $2.4 million decrease in operating

lease liability, offset by a $7.3 million increase in accounts payable, $1.5 million increase in accrued expenses and other current liabilities and a $1.3 million decrease in accounts receivable.

Cash used in investing activities

During the year ended December 31, 2024, cash used in investing activities of $554.4 million was primarily comprised of purchases of marketable securities of $2.1 billion and purchases of property and equipment of $10.3 million, offset by cash provided by maturities of marketable securities of $1.6 billion.

During the year ended December 31, 2023, cash used in investing activities of $342.6 million was primarily comprised of purchases of marketable securities of $1.1 billion and purchases of property and equipment of $7.7 million, offset by cash provided by maturities of marketable securities of $724.0 million.

During the year ended December 31, 2022, cash used in investing activities of $24.1 million was primarily comprised of purchases of marketable securities of $612.8 million and purchases of property and equipment of $10.8 million, offset by cash provided by maturities of marketable securities of $599.5 million.

Cash provided by financing activities

During the year ended December 31, 2024, cash provided by financing activities of $959.4 million was comprised of $823.0 million in net proceeds from the issuance of common stock and pre-funded warrants from the December 2024 underwritten public offering, $118.7 million in net proceeds from the issuance of common stock under the 2024 ATM and the 2021 ATM, $12.3 million in proceeds from the issuance of common stock upon the exercise of stock options and $5.0 million in proceeds from the issuance of common stock under the employee stock purchase plan.

During the year ended December 31, 2023, cash provided by financing activities of $1.2 billion was comprised of $840.8 million of cash, cash equivalents and restricted cash acquired, net of $20.7 million transaction costs in connection with the EQRx Acquisition, $323.7 million in net proceeds from the March 2023 underwritten public offering, $62.1 million in net proceeds from the issuance of common stock under the 2021 ATM, $3.3 million in proceeds from the issuance of common stock under the employee stock purchase plan and $3.3 million in proceeds from the issuance of common stock upon the exercise of stock options, offset by $4.0 million in tax payments in satisfaction of withholding tax requirements pursuant to the EQRx Acquisition.

During the year ended December 31, 2022, cash provided by financing activities of $301.4 million was comprised of $248.1 million in net proceeds from the July 2022 underwritten public offering, $49.9 million in net proceeds from the issuance of common stock under the 2021 ATM, $1.9 million in proceeds from the issuance of common stock under the employee stock purchase plan and $1.5 million in proceeds from the issuance of common stock upon the exercise of stock options.

Contractual Obligations and Commitments

We have contractual obligations related to our office and laboratory space lease in Redwood City, California, described in "Note 7. Commitments and contingencies" in the "Notes to Consolidated Financial Statements" contained in Part II, Item 8 of this Annual Report on Form 10-K.

We enter into agreements in the ordinary course of business with contract research organizations for clinical trials, contract manufacturing organizations to provide clinical trial materials and with vendors for preclinical studies and other services and products for operating purposes which are generally cancelable at any time by us upon 30 to 90 days prior written notice.

Indemnification Agreements

We enter into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, we indemnify, hold harmless and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments we could be required to make under these arrangements is not determinable. We have never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, we believe the fair value of these agreements is minimal.

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 consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles (U.S.

GAAP). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue recognition

We recognize revenue in accordance with Accounting Standards Codification Topic 606, Revenue from Contracts with Customers (ASC 606). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which such entity expects to receive in exchange for those goods or services. In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under arrangements, we perform the following steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies the performance obligation. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

We enter into collaboration agreements under which we may obtain upfront license fees, research and development funding, and development, regulatory and commercial milestone payments and royalty payments. Our performance obligations under these arrangements may include licenses of intellectual property, sales and distribution rights, research and development services, delivery of manufactured product and/or participation on joint steering committees.

Licenses of intellectual property: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from upfront license fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring proportional performance for purposes of recognizing revenue from non-refundable, upfront fees. We evaluate the measure of proportional performance each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Research, development and regulatory milestone payments: At the inception of each arrangement that includes research, development, or regulatory milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price. We use the most likely amount method for research, development and regulatory milestone payments. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price.

Sales-based milestones and royalties: For arrangements that include sales-based milestone or royalty payments based on the level of sales, and in which the license is deemed to be the predominant item to which the sales-based milestone or royalties relate to, we recognize revenue in the period in which the sales-based milestone is achieved and in the period in which the sales associated with the royalty occur. To date, we have not recognized any sales-based milestone or royalty revenue resulting from our collaboration arrangements.

The transaction price for each collaboration agreement is determined based on the amount of consideration we expect to be entitled for satisfying all performance obligations within the agreement. Significant judgment may be required in determining the amount of variable consideration to be included in the transaction price. We use the most likely amount method to determine variable consideration and will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Revenue is recognized based on actual costs incurred as a percentage of total estimated costs to be incurred over the performance obligation as we fulfill our performance obligations. A cost-based input method of revenue recognition requires management to make estimates of costs to complete our performance obligations. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to fulfill our performance obligations will be recorded in the period in which changes are identified and amounts can be reasonably estimated.

Accrued research and development expenses

We accrue for estimated costs of research and development activities performed by third-party service providers, which include pre-clinical studies, clinical trials and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated services provided but not yet invoiced and include these costs in accrued expenses and other payables in our consolidated balance sheets and within research and development expense in our consolidated statements of operations. We accrue for these costs based on various factors such as estimates of the work completed and in accordance with agreements established with our third-party service providers. Further, we accrue expenses related to clinical trials based on the level of patient enrollment and activity according to the related agreement. We monitor patient enrollment levels and related activity to the extent reasonably possible and make judgments and estimates in determining the accrued balance in each reporting period. If we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not experienced significant changes in our estimates of preclinical studies and clinical trial accruals.

Stock-based compensation

We maintain an equity incentive plan as a long-term incentive for employees, consultants and members of our board of directors. The plan allows for the issuance of non-statutory options (NSOs), incentive stock options (ISOs), restricted stock unit awards (RSUs) to employees and NSOs and RSUs to nonemployees.

Stock-based compensation is measured using estimated grant date fair value and recognized as compensation expense over the service period in which the awards are expected to vest. The grant date fair value of an RSU award is based on our stock price on the date of grant. For options, we estimate the grant date fair value, and the resulting stock-based compensation, using the Black-Scholes option-pricing model, and we use the straight-line method for expense attribution. The Black-Scholes model requires us to make assumptions and judgments about the variables used in the calculations, including the expected term (weighted-average period of time that the options granted are expected to be outstanding), the expected volatility of our common stock, the related risk-free interest rate and the expected dividend. We have elected to recognize forfeitures of stock-based awards as they occur.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to determine the fair value of stock-based awards. These assumptions include:

- *Expected Term*—The expected term is calculated using the simplified method, which is available where there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method.
- *Expected Volatility*—Given that we do not have sufficient trading history for our common stock, the expected volatility was estimated based on the average volatility of the Company and comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.
- *Expected Dividend*—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

Recent Accounting Pronouncements

For a description of the expected impact of recent accounting pronouncements, see "Note 2. Summary of significant accounting policies" in the "Notes to Consolidated Financial Statements" contained in Part II, Item 8 of this Annual Report on Form 10-K.

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

Interest rate risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income

from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality and short-term duration, invested in compliance with our policy.

We held cash, cash equivalents and marketable securities of $2.3 billion and $1.9 billion as of December 31, 2024 and 2023, respectively, which consisted of bank deposits, money market funds, U.S. government debt securities, U.S. government agency bonds, commercial paper and corporate bonds. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us. Due to the short-term maturities of our cash equivalents and marketable securities, an immediate one percent change in interest rates would not have a material effect on the fair value of our cash equivalents and marketable securities.

Foreign currency risk

Our expenses are generally denominated in U.S. dollars. However, we have entered into a limited number of contracts with vendors for research and development services with payments denominated in foreign currencies, including the Euro, British Pound and Chinese Yuan. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. A 10% increase or decrease in current exchange rates would not have a material effect on our financial results.

Item 8. Financial Statements and Supplementary Data.

REVOLUTION MEDICINES, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Revolution Medicines, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Revolution Medicines, Inc. and its subsidiaries (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2024, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's 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. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

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

External Research and Development Costs.

As described in Note 2 to the consolidated financial statements, research and development expenses consist of costs incurred for the Company's own research and development activities and are expensed as incurred. Research and development costs consist of salaries and benefits, including associated stock-based compensation, and laboratory supplies and facility costs, as well as external costs paid to other entities that conduct certain research and development activities on the Company's behalf. As disclosed by management, certain development activities are based on an evaluation of the progress to completion of specific tasks using information and data provided to the Company by its vendors, collaborators and third-party service providers. Management estimates research and development expenses based on estimates of services performed and relies on third party contractors and vendors to provide timely and accurate estimates of expenses of services performed to assist in these estimates. The Company's research and development expense for the year ended December 31, 2024, was $592.2 million, a majority of which relates to external research and development costs.

The principal consideration for our determination that performing procedures relating to external research and development costs is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's external research and development costs.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to external research and development costs. These procedures also included, among others, testing external research and development costs on a sample basis by obtaining and inspecting source documents, such as the underlying contract research organization agreements, purchase orders, invoices received, and information received from certain third party service providers, where applicable.

/s/ PricewaterhouseCoopers LLP
San Jose, California
February 26, 2025

We have served as the Company's auditor since 2017.

REVOLUTION MEDICINES, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 543,064	$ 696,148
Marketable securities	1,746,235	1,156,807
Accounts receivable	—	1,254
Prepaid expenses and other current assets	38,333	25,072
Total current assets	2,327,632	1,879,281
Property and equipment, net	24,289	22,865
Operating lease right-of-use asset	117,534	77,149
Intangible assets, net	56,670	57,739
Goodwill	14,608	14,608
Restricted cash	3,698	3,031
Other noncurrent assets	13,870	7,032
Total assets	$ 2,558,301	$ 2,061,705
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 54,427	$ 61,788
Accrued expenses and other current liabilities	96,615	74,694
Operating lease liability, current	12,872	7,369
Total current liabilities	163,914	143,851
Deferred tax liability	2,353	3,115
Operating lease liability, noncurrent	122,971	80,575
Warrant liability	3,189	6,512
Other noncurrent liabilities	670	1,458
Total liabilities	293,097	235,511
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2024 and December 31, 2023, respectively; none issued and outstanding at December 31, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of December 31, 2024 and December 31, 2023, respectively; 185,896,625 and 170,234,594 shares issued as of December 31, 2024 and December 31, 2023; 185,896,625 and 164,674,594 shares outstanding as of December 31, 2024 and December 31, 2023, respectively	18	16
Additional paid-in capital	4,001,666	2,963,342
Accumulated other comprehensive income	1,321	544
Accumulated deficit	(1,737,801)	(1,137,708)
Total stockholders' equity	2,265,204	1,826,194
Total liabilities and stockholders' equity	$ 2,558,301	$ 2,061,705

The accompanying notes are an integral part of these Consolidated Financial Statements.

REVOLUTION MEDICINES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Year Ended December 31,		
	2024	2023	2022
Revenue:			
Collaboration revenue	$ —	$ 11,580	$ 35,380
Total revenue	—	11,580	35,380
Operating expenses:			
Research and development	592,225	423,144	253,073
General and administrative	97,299	75,621	40,586
Total operating expenses	689,524	498,765	293,659
Loss from operations	(689,524)	(487,185)	(258,279)
Other income (expense), net:			
Interest income	86,883	47,482	9,154
Other expense	(2,528)	(303)	—
Change in fair value of warrant liability and contingent earn-out shares	4,323	115	—
Total other income, net	88,678	47,294	9,154
Loss before income taxes	(600,846)	(439,891)	(249,125)
Benefit from income taxes	753	3,524	420
Net loss	$ (600,093)	$ (436,367)	$ (248,705)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.58)	$ (3.86)	$ (3.08)
Weighted-average common shares used to compute net loss per share, basic and diluted	167,737,672	113,149,869	80,626,525
Comprehensive loss:			
Net loss	$ (600,093)	$ (436,367)	$ (248,705)
Other comprehensive income (loss):			
Unrealized gain (loss) on investments, net	777	2,324	(1,404)
Comprehensive loss	$ (599,316)	$ (434,043)	$ (250,109)

The accompanying notes are an integral part of these Consolidated Financial Statements.

REVOLUTION MEDICINES, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income/ (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	74,142,619	$ 8	$ 1,055,572	$ (376)	$ (452,636)	$ 602,568
Issuance of common stock pursuant to stock option exercises	249,544	—	1,481	—	—	1,481
Issuance of common stock from follow-on public offering, net of offering costs of $16,374	13,225,000	1	248,125	—	—	248,126
Issuance of common stock related to vesting of restricted stock units	278,848	—	—	—	—	—
Issuance of common stock related to employee stock purchase plan	130,327	—	1,864	—	—	1,864
Issuance of common stock from at-the-market offering	2,385,846	—	49,919	—	—	49,919
Repurchases of early exercised stock	(272)	—	—	—	—	—
Vesting of early exercised stock options	—	—	143	—	—	143
Stock-based compensation expense	—	—	31,196	—		31,196
Net unrealized loss on marketable securities	—	—	—	(1,404)	—	(1,404)
Net loss	—	—	—	—	(248,705)	(248,705)
Balance at December 31, 2022	90,411,912	$ 9	$ 1,388,300	$ (1,780)	$ (701,341)	$ 685,188
Issuance of common stock pursuant to stock option exercises	524,094	—	3,316	—	—	3,316
Issuance of common stock from follow-on public offering, net of offering costs of $21,294	15,681,818	2	323,704	—	—	323,706
Issuance of common stock in connection with acquisition of EQRx, Inc., net of transaction costs of $20,717	54,786,528	5	1,120,880	—	—	1,120,885
Issuance of common stock from at-the-market offering	2,482,880	—	62,053	—	—	62,053
Issuance of common stock related to vesting of restricted stock units	576,974	—	—	—	—	—
Issuance of common stock related to employee stock purchase plan	210,679	—	3,317	—	—	3,317
Repurchases of early exercised stock	(291)	—	—	—	—	—
Stock-based compensation expense	—	—	61,772	—	—	61,772
Net unrealized gain on marketable securities	—	—	—	2,324	—	2,324
Net loss	—	—	—	—	(436,367)	(436,367)
Balance at December 31, 2023	164,674,594	$ 16	$ 2,963,342	$ 544	$ (1,137,708)	$ 1,826,194
Issuance of common stock pursuant to stock option exercises	927,275	—	12,330	—	—	12,330
Issuance of common stock from follow-on public offering, net of offering costs of $34,881	16,576,088	2	727,618	—	—	727,620
Issuance of pre-funded warrants, net of issuance costs of $4,578	—	—	95,422	—	—	95,422
Issuance of common stock from at-the-market offering	2,441,943	—	118,728	—	—	118,728
Issuance of common stock related to vesting of restricted stock units	1,011,255	—	—	—	—	—
Issuance of common stock related to employee stock purchase plan	265,470	—	5,029	—	—	5,029
Stock-based compensation expense	—	—	79,197	—	—	79,197
Net unrealized gain on marketable securities	—	—	—	777	—	777
Net loss	—	—	—	—	(600,093)	(600,093)
Balance at December 31, 2024	185,896,625	$ 18	$ 4,001,666	$ 1,321	$ (1,737,801)	$ 2,265,204

The accompanying notes are an integral part of these Consolidated Financial Statements.

REVOLUTION MEDICINES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2024	2023	2022
Cash flows from operating activities			
Net loss	$ (600,093)	$ (436,367)	$ (248,705)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss on disposal of fixed assets	118	52	19
Amortization of intangible assets	1,069	1,068	1,069
Stock-based compensation expense	79,197	61,772	31,196
Depreciation and amortization	6,559	5,042	3,972
Change in fair value of warrant liability and contingent earn-out shares	(4,323)	115	—
Net amortization of premium or discount on marketable securities	(44,565)	(22,205)	(3,078)
Amortization of operating lease right-of-use asset	4,196	3,199	4,615
Changes in operating assets and liabilities:			
Accounts receivable	1,254	3,419	1,256
Prepaid expenses and other current assets	(9,698)	(2,646)	(3,779)
Accounts payable	(6,465)	32,469	7,288
Accrued expenses and other current liabilities	21,985	14,668	1,502
Deferred revenue	—	(4,459)	(14,472)
Operating lease liability	(245)	(1,532)	(2,428)
Deferred tax liability	(762)	(3,910)	(419)
Other noncurrent assets	(5,875)	(1,414)	(2,247)
Other noncurrent liabilities	212	157	(190)
Net cash used in operating activities	(557,436)	(350,572)	(224,401)
Cash flows from investing activities			
Purchases of marketable securities	(2,136,623)	(1,058,916)	(612,769)
Maturities of marketable securities	1,592,537	724,047	599,469
Purchases of property and equipment	(10,308)	(7,729)	(10,816)
Net cash used in investing activities	(554,394)	(342,598)	(24,116)
Cash flows from financing activities			
Cash, cash equivalents and restricted cash acquired in connection with EQRx Acquisition, net of transaction costs	—	840,834	—
Proceeds from issuance of common stock, net of issuance costs	727,620	323,706	248,126
Proceeds from issuance of pre-funded warrants, net of transaction costs	95,422	—	—
Proceeds from issuance of common stock from at-the-market offering, net of transaction costs	118,728	62,053	49,919
Proceeds from issuance of common stock under equity incentive plans	12,330	3,316	1,481
Proceeds from issuance of common stock related to employee stock purchase plan	5,029	3,317	1,864
Tax payment for common stock withheld in satisfaction of withholding tax requirements	—	(4,026)	—
Payments of deferred offering costs	284	—	42
Net cash provided by financing activities	959,413	1,229,200	301,432
Net increase (decrease) in cash, cash equivalents and restricted cash	(152,417)	536,030	52,915
Cash, cash equivalents and restricted cash - beginning of year	699,179	163,149	110,234
Cash, cash equivalents and restricted cash - end of year	$ 546,762	$ 699,179	$ 163,149
Reconciliation of cash, cash equivalents and restricted cash to consolidated balance sheets			
Cash and cash equivalents	543,064	696,148	161,412
Restricted cash	3,698	3,031	1,737
Cash, cash equivalents and restricted cash - end of period	$ 546,762	$ 699,179	$ 163,149
Supplemental disclosure of non-cash investing and financing activities			
Issuance of common stock for EQRx acquisition	$ —	$ 1,085,676	$ —
Fair value of net assets acquired in connection with EQRx Acquisition	—	291,475	—
Purchases of property and equipment in accounts payable and accrued expenses and other current liabilities	1,576	2,611	1,419
Right-of-use assets obtained in exchange for operating lease liabilities	44,581	25,271	—

The accompanying notes are an integral part of these Consolidated Financial Statements.

1. Organization

Revolution Medicines, Inc. (the Company) is a clinical-stage precision oncology company focused on developing novel targeted therapies for RAS-addicted cancers. The Company was founded in October 2014 and is headquartered in Redwood City, California.

Liquidity

The Company has incurred net operating losses in each year since inception. As of December 31, 2024, the Company had an accumulated deficit of $1.7 billion. Management believes that its existing cash, cash equivalents and marketable securities will enable the Company to fund its planned operations for at least 12 months following the issuance date of these consolidated financial statements. The Company has been able to fund its operations through the issuance and sale of common stock and redeemable convertible preferred stock, the acquisition of EQRx, Inc. (EQRx), and upfront payments and research and development cost reimbursement received under the Company's prior collaboration agreement with Genzyme Corporation, an affiliate of Sanofi. Future capital requirements will depend on many factors, including the timing and extent of spending on research and development. There can be no assurance that, in the event the Company requires additional financing, such financing will be available at terms acceptable to the Company, if at all. Failure to generate sufficient cash flows from operations, raise additional capital and reduce discretionary spending should additional capital not become available could have a material adverse effect on the Company's ability to achieve its business objectives.

Public offerings

In July 2022, the Company issued and sold 13,225,000 shares of its common stock in an underwritten public offering (including the exercise in full by the underwriters of their option to purchase an additional 1,725,000 shares of the Company's common stock) at a price to the public of $20.00 per share, for net proceeds of $248.1 million, after deducting underwriting discounts and commissions of $15.9 million and expenses of $0.5 million.

In March 2023, the Company issued and sold 15,681,818 shares of its common stock in an underwritten public offering (including the exercise in full by the underwriters of their option to purchase an additional 2,045,454 shares of the Company's common stock) at a price to the public of $22.00 per share, for net proceeds of $323.7 million, after deducting underwriting discounts and commissions of $20.7 million and expenses of $0.6 million.

In December 2024, the Company issued and sold in an underwritten public offering (i) 16,576,088 shares of its common stock in an underwritten public offering (including the exercise in full by the underwriters of their option to purchase an additional 2,445,652 shares of the Company's common stock) at a price to the public of $46.00 per share and (ii) pre-funded warrants to certain investors to purchase an aggregate of 2,173,917 shares of the Company's common stock at a price of $45.9999 per pre-funded warrant. Each pre-funded warrant will be exercisable from the date of issuance until fully exercised, subject to an ownership limitation. Total net proceeds were $823.0 million, after deducting underwriting discounts and commissions of $38.8 million and expenses of $0.6 million.

In November 2021, the Company entered into a sales agreement with Cowen and Company, LLC, an affiliate of TD Securities (USA) LLC (TD Cowen), as amended in March 2024, to sell shares of its common stock, from time to time, with aggregate gross proceeds of up to $250 million, through an at-the-market equity offering program (the 2021 ATM Program). During the year ended December 31, 2022, the Company sold an aggregate of 339,302 shares of common stock under the 2021 ATM Program resulting in gross proceeds to the Company of $10.4 million, with net proceeds to the Company of $10.1 million after deducting commissions and expenses. During the year ended December 31, 2023, the Company sold an aggregate of 2,482,880 shares of common stock under the 2021 ATM Program resulting in gross proceeds to the Company of $63.5 million, with net proceeds to the Company of $62.1 million after deducting commissions and expenses. During the year ended December 31, 2024, the Company sold an aggregate of 1,294,050 shares of common stock under the 2021 ATM Program, resulting in gross proceeds of $60.8 million, with net proceeds to the Company of $59.2 million after deducting commissions and expenses.

In August 2024, the Company entered into a new sales agreement with TD Cowen to sell shares of the Company's common stock, from time to time, with aggregate gross proceeds of up to $500 million, through an at-the-market equity offering program (the 2024 ATM Program). The 2024 ATM Program replaced the 2021 ATM Program and any unused balance remaining under the 2021 ATM Program is no longer available. During the year ended December 31, 2024, the Company sold an aggregate of 1,147,893 shares

of common stock under the 2024 ATM Program, resulting in gross proceeds of $60.4 million, with net proceeds to the Company of $59.5 million after deducting commissions and expenses.

2. Summary of significant accounting policies

Basis of presentation

The consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States (GAAP) and applicable rules of the Securities and Exchange Commission (SEC) regarding financial reporting and, in the opinion of management, include all normal and recurring adjustments which are necessary to state fairly the Company's financial position and results of operations for the reported periods. The consolidated financial statements for the years ended December 31, 2024, 2023 and 2022 include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The functional and reporting currency of the Company and its subsidiaries is the U.S. dollar.

Use of estimates

The preparation of consolidated 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 as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including the fair value of assets acquired and liabilities assumed and related purchase price allocation, revenue recognition, clinical accruals, income taxes, useful lives of property and equipment and intangible assets, impairment of goodwill and intangibles, impairment of in-process research and development and developed technologies, the incremental borrowing rate for determining operating lease assets and liabilities, warrant liabilities and stock-based compensation. Estimates are based on historical experience, complex judgments, facts and circumstances available at the time and various other assumptions that are believed to be reasonable under the circumstances but are inherently uncertain and unpredictable. Actual results could materially differ from the Company's estimates, and there may be changes to the estimates in future periods.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less at the date of purchase to be cash equivalents. Cash equivalents consist of amounts invested in money market funds, commercial paper, government securities and corporate bonds with original maturities of three months or less at the date of purchase.

Marketable securities

Investments in marketable securities primarily consist of U.S. government debt securities, U.S. government agency bonds, commercial paper, and corporate bonds. The Company has classified its marketable securities as available-for-sale and may sell these securities prior to their stated maturities. The Company views these marketable securities as available to support current operations and classifies marketable securities with maturities beyond 12 months as current assets. The Company's investments in marketable securities are carried at estimated fair value, which is derived from independent pricing sources based on quoted prices in active markets for similar securities. Unrealized gains and losses are reported as a component of accumulated other comprehensive income (loss). The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income on the consolidated statements of operations and comprehensive loss. Realized gains and losses are included in interest income on the consolidated statements of operations and comprehensive loss.

The Company periodically evaluates its investments to assess whether those with unrealized loss positions are other than temporarily impaired. The Company considers various factors in determining whether to recognize an impairment charge. If the Company determines that the decline in an investment's fair value is other-than-temporary, the difference is recognized as an impairment loss in the consolidated statements of operations and comprehensive loss. As of December 31, 2024, no other-than-temporary-impairment has been recorded.

Restricted cash

As of December 31, 2024 and 2023, the Company had $3.7 million and $3.0 million, respectively, of noncurrent restricted cash related to Company issued letters of credit in connection with leases. These amounts are held in separate bank accounts to support letter of credit agreements for certain of its leases.

Concentration of credit risk and other risks and uncertainties

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash, cash equivalents and marketable securities. The Company maintains bank deposits in federally insured financial institutions and these deposits may exceed federally insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its bank deposits and issuers of its investments. The Company's investment policy limits investments to money market funds, certain types of debt securities issued by the U.S. government and its agencies, certificates of deposit, corporate debt and commercial paper, and places restrictions on the credit ratings, maturities and concentration by type and issuer. The Company has not experienced any significant losses on its deposits of cash and cash equivalents or investments.

Fair value measurement

The carrying amounts of the Company's certain financial instruments, including cash equivalents, accounts payable and accrued expenses and other current liabilities approximate fair value due to their relatively short maturities and market interest rates, if applicable. For more information, refer to Note 4 regarding the fair value of the Company's available-for-sale securities.

Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active; and

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Property and equipment, net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed on a straight-line basis over the estimated useful lives of the related assets, which is generally three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the assets' estimated useful lives or the remaining term of the lease. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the consolidated balance sheet and the resulting gain or loss is reflected in the consolidated statement of operations.

Useful lives of property and equipment are as follows:

Property and equipment	**Estimated useful life**
Laboratory equipment	4-5 years
Leasehold improvements	Lesser of estimated useful life or remaining lease term
Computer equipment and software	3 years
Furniture and fixtures	5 years

Leases

The Company determines if an arrangement is, or contains, a lease at inception and then classifies the lease as operating or financing based on the underlying terms and conditions of the contract. Leases with terms greater than one year are initially recognized on the balance sheet as right-of-use assets and lease liabilities based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the incremental borrowing rate, which is the rate incurred to borrow, on a collateralized basis, an amount equal to the lease payments over a similar term and in a similar economic environment of the applicable country or region. Variable lease payments are excluded from the right-of-use assets and operating lease liabilities and are recognized in the period in which the obligation for those payments is incurred. Leases with a term of 12 months or less are not recognized on the consolidated balance sheets.

Impairment of long-lived assets

Long-lived assets are reviewed for indications of possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. Recoverability is measured by comparison of the carrying amounts of the asset group to the future undiscounted cash flows attributable to these assets. An impairment loss is recognized to the extent an asset group is not recoverable, and the carrying amount exceeds the projected discounted future cash flows arising from these assets. There were no impairments of long-lived assets for any of the periods presented.

Acquired intangible assets

Indefinite-lived intangible assets represent the estimated fair value assigned to in-process research and development (IPR&D) acquired in a business combination. The Company reviews indefinite-lived intangible assets for impairment at least annually or more frequently if events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. If the carrying value of an indefinite-lived intangible asset exceeds its fair value, then it is written down to its adjusted fair value. As of December 31, 2024, there have been no such impairments. For IPR&D, if a product candidate derived from the indefinite-lived intangible asset is developed and commercialized, the useful life will be determined, and the carrying value will be amortized prospectively over that estimated useful life. Alternatively, if a product candidate is abandoned, the carrying value of the intangible asset will be charged to research and development expenses in the consolidated statements of operations and comprehensive loss.

Finite-lived intangible assets acquired in a business combination are recognized separately from goodwill and are initially recognized at their fair value at the acquisition date and are carried at cost less accumulated amortization and impairment. Amortization is computed using the straight-line method over the estimated useful lives of the respective finite-lived intangible assets and is included in research and development expenses in the consolidated statement of operations. Intangible assets are reviewed for impairment at least annually or more frequently if indicators of potential impairment exist. As of December 31, 2024, no such impairment has been recorded.

Goodwill

Goodwill represents the excess of the purchase price over the estimated fair value of the net tangible and intangible assets acquired in a business combination. The Company reviews goodwill for impairment at least annually or more frequently if events or changes in circumstances indicate that the carrying value of goodwill may not be recoverable. Goodwill is tested for impairment at the reporting unit level by first assessing the qualitative factors to determine whether it is more likely than not that the fair value of the Company's single reporting unit is less than its carrying amount. Qualitative indicators assessed include consideration of macroeconomic, industry and market conditions, the Company's overall financial performance and personnel or strategy changes. Based on the qualitative assessment, if it is determined that it is more likely than not that its fair value is less than its carrying amount, the fair value of the Company's single reporting unit is compared to its carrying value. Any excess of the goodwill carrying amount over the fair value is recognized as an impairment loss, and the carrying value of goodwill is written down to fair value. As of December 31, 2024, no goodwill impairment has been identified.

Warrants

Warrants assumed as part of the EQRx transaction as described in Note 3 contain provisions that require them to be classified as derivative liabilities in accordance with Accounting Standards Codification Topic 815, Derivatives and Hedging (ASC 815). Accordingly, at the end of each reporting period, changes in fair value during the period are recognized as a change in fair value of warrant liabilities within the consolidated statements of operations and comprehensive loss. The Company adjusts the warrant liabilities for changes in the fair value until the earlier of (a) the exercise or expiration of the warrants or (b) the redemption of the warrants, at which time the warrants will be reclassified to additional paid-in capital.

Derivative warrant liabilities are classified as noncurrent liabilities, as their liquidation is not reasonably expected to require the use of current assets or require the creation of current liabilities.

Revenue recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of Accounting Standards Codification Topic 606, Revenue from Contracts with Customers (ASC 606), the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into collaboration agreements under which it may obtain upfront license fees, research and development funding, and development, regulatory and commercial milestone payments and royalty payments. The Company's performance obligations under these arrangements may include licenses of intellectual property, sales and distribution rights, research and development services, delivery of manufactured product and/or participation on joint steering committees.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from upfront license fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring proportional performance for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of proportional performance each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Research, development and regulatory milestone payments: At the inception of each arrangement that includes research, development, or regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. The Company uses the most likely amount method for research, development and regulatory milestone payments. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price.

Sales-based milestones and royalties: For arrangements that include sales-based milestone or royalty payments based on the level of sales, and in which the license is deemed to be the predominant item to which the sales-based milestone or royalties relate to, the Company recognizes revenue in the period in which the sales-based milestone is achieved and in the period in which the sales associated with the royalty occur. To date, the Company has not recognized any sales-based milestone or royalty revenue resulting from its collaboration arrangements.

Deferred revenue represents amounts received by the Company for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met. The current portion of deferred revenue represents the amount to be recognized within one year from the balance sheet date based on the estimated performance period of the underlying performance obligation. The noncurrent portion of deferred revenue represents amounts to be recognized after one year through the end of the performance period of the performance obligation.

Research and development expenditures

Research and development expenses consist of costs incurred for the Company's own and for collaborative research and development activities. Research and development costs are expensed as incurred. Research and development costs consist of salaries and benefits, including associated stock-based compensation, and laboratory supplies and facility costs, as well as external costs paid to other entities that conduct certain research and development activities on the Company's behalf. The Company estimates preclinical studies and clinical trial expenses based on the services performed pursuant to contracts with research institutions, contract research organizations and clinical manufacturing organizations that conduct and manage preclinical studies and clinical trials on the Company's behalf based on actual time and expenses incurred by them. Further, the Company accrues expenses related to clinical

trials based on the level of patient activity according to the related agreement. The Company monitors patient enrollment levels and related activity to the extent reasonably possible and adjusts estimates accordingly.

Stock-based compensation

The Company measures its stock-based awards granted to employees and directors based on the estimated fair values of the awards and recognizes the compensation on a straight-line basis over the requisite service period. The fair value of options issued under the employee stock purchase plan is calculated using the Black-Scholes option-pricing model. Restricted stock units are valued based on the closing price of the Company's common stock on the date of grant.

Comprehensive loss

For the years ended December 31, 2024, 2023 and 2022, other comprehensive income (loss) included net unrealized gains or losses on marketable securities.

Income taxes

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Management makes an assessment of the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's historical operating performance and the recorded cumulative net losses in prior fiscal periods, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Changes in recognition or measurement are reflected in the period in which a change in facts occurs. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of interest expense.

Net loss per share attributable to common stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock (including pre-funded warrants) outstanding during the period, without consideration for potentially dilutive securities. Shares of common stock into which the pre-funded warrants may be exercised are considered outstanding for the purposes of computing net loss per share because the shares may be issued for little or no consideration, are fully vested and are exercisable without being subject to any conditions after the original issuance date. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock, stock options, common stock subject to repurchase related to unvested restricted stock awards and early exercise of stock options are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock is considered a participating security because it participates in dividends with common stock. The Company also considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of all series of redeemable convertible preferred stock and the holders of early exercised shares subject to repurchase do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share for those periods.

Segment reporting

The Company determines its operating segments based on how the chief operating decision maker (CODM) views and analyzes the segment's operations and performance and allocates resources. The President and Chief Executive Officer is the CODM. The CODM utilizes net loss as the measure of segment profit or loss. The Company has one operating and reportable segment. The Company's CODM manages the Company's operations on a consolidated basis for the purposes of allocating resources and evaluating financial performance. The CODM assesses performance for and decides how to allocate resources based on the company's cash and investment balance, periodic changes in cash and investments, and net loss, all of which are reported on the company's consolidated

balance sheets, statements of operations and/or statements of cash flows. The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets. All of the Company's long-lived assets are located in the United States.

In addition to the significant expense categories included within consolidated net loss presented on the Company's Consolidated Statements of Operations, see below for disaggregated amounts that comprise research and development expenses:

	Years Ended December 31,		
	2024	2023	2022
	(in thousands)		
Third-party research and development expenses[(a)]	$ 368,101	$ 262,605	$ 153,944
Salaries and other employee-related expenses	113,475	81,658	49,449
Stock-based compensation expense	50,973	34,126	18,113
Amortization of intangible assets	1,069	1,068	1,069
Other research and development costs	58,607	43,687	30,498
Total research and development expense	$ 592,225	$ 423,144	$ 253,073

[(a)] Third-party research and development expenses are comprised primarily of external costs incurred under agreements with third-party contract organizations, investigative clinical trial sites that conduct research and development activities on the Company's behalf and consultants; costs related to the production of preclinical, clinical and pre-launch materials, including fees paid to contract manufacturers; and laboratory and vendor expenses related to the execution of discovery programs, preclinical and clinical trials.

Recent accounting pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB), under its ASC or other standard setting bodies, and adopted by the Company as of the specified effective date.

Recently adopted accounting pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures (ASU 2023-07). ASU 2023-07 improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The guidance is effective for public business entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years, beginning after December 15, 2024. Early application is permitted. The guidance is to be applied retrospectively to all prior periods presented in the financial statements. Upon transition, the segment expense categories and amounts disclosed in the prior periods should be based on the significant segment expense categories identified and disclosed in the period of adoption. The Company adopted the standard for the year ended December 31, 2024 with disclosures included in Note 2, Summary of significant accounting policies.

Recently announced accounting pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740), Improvements to Income Tax Disclosures (ASU 2023-09). ASU 2023-09 relates to rate reconciliation and income taxes paid disclosures. The guidance is effective for public business entities for fiscal years beginning after December 15, 2024. Early application is permitted. The guidance is to be applied on a prospective basis. The Company is currently evaluating the impact of the standard on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses (DISE). The new standard requires disclosures about specific types of expenses included in the expense captions presented on the face of the income statement as well as disclosures about selling expenses. The guidance is effective for public business entities for fiscal years (clarified as annual reporting periods by ASU 2025-01, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures Subtopic 220-40 issued in January 2025) beginning after December 15, 2026, and interim periods beginning after December 15, 2027. Early adoption is permitted. The guidance is to be applied prospectively, with the option for retrospective application. The Company is currently evaluating the impact of the standard on its consolidated financial statements.

3. Acquisition

On November 9, 2023 (the Closing Date), the Company completed the acquisition of EQRx (the EQRx Acquisition). Pursuant to the Agreement and Plan of Merger, dated as of July 31, 2023 (the Merger Agreement), EQRx, LLC survived as a wholly owned subsidiary of the Company.

On the Closing Date, each share of EQRx common stock issued and outstanding immediately prior to the completion of the EQRx Acquisition was converted into the right to receive 0.1112 shares of the Company's common stock. Outstanding stock options, restricted stock units and restricted stock awards of EQRx were also converted into the Company's common stock, subject to the terms of the Merger Agreement. The Company issued 54.8 million shares of the Company's common stock and paid $4.0 million in taxes to satisfy statutory income tax withholding obligations in conjunction with the EQRx Acquisition.

The EQRx Acquisition provided the Company with additional financing through the acquisition of EQRx's cash, cash equivalents, and marketable securities, which comprised the majority of the net assets acquired from EQRx. As the Company primarily acquired these monetary assets, the EQRx Acquisition was accounted for as a capital-raising transaction with an asset acquisition component. EQRx does not meet the definition of a business under Financial Accounting Standards Board's Accounting Standards Codification Topic 805, Business Combinations (ASC 805), due to the fair value of EQRx, excluding cash and cash equivalents, as of the date of the EQRx Acquisition, being concentrated primarily in one asset class, marketable securities.

Under the asset acquisition method of accounting, the purchase consideration was allocated and recorded by the Company on a fair value basis to the net assets acquired on the Closing Date. Any excess fair value of net assets of EQRx over the cost of the acquisition following determination of the actual purchase consideration is allocated to EQRx's qualifying assets under ASC 805. As there were no qualifying assets acquired the excess fair value of net assets under ASC 805 was recorded to equity, as a capital-raising transaction. Because EQRx had wound down the majority of its research and development activities and its operations by the time of the Closing Date, the net assets being acquired are primarily comprised of cash and cash equivalents and marketable securities.

The following table reflects the consideration transferred by the Company:

	Amount (in thousands)
Fair value of shares of combined company to be owned by EQRx stockholders (1)	$ 1,096,826
Less: Fair value of EQRx equity awards converting to Revolution Medicines common stock attributable to post-combination service	(11,150)
Taxes paid by Revolution Medicines on behalf of EQRx to satisfy statutory income tax withholding obligations	4,026
Fair value of warrants	6,907
Fair value of contingent earn-out shares	490
Purchase price	**$ 1,097,099**

(1) Represents the fair value of approximately 54.8 million shares of Revolution Medicines common stock issued, calculated using the per share price of Revolution Medicines common stock of $20.02 as of November 9, 2023.

The following table summarizes the fair value of the assets acquired and liabilities assumed as of the Closing Date:

	Amount (in thousands)
Cash and cash equivalents	$ 860,918
Marketable securities	313,878
Prepaid expenses and other current assets	12,084
Restricted cash	633
Other noncurrent assets	2,912
Accounts payable	(6,893)
Accrued expenses and other current liabilities	(30,506)
Net assets acquired	**$ 1,153,026**

The excess fair value of net assets acquired over the purchase price was $55.9 million and was recorded to additional paid-in capital.

The following table calculates the excess of fair value of assets acquired over the purchase consideration under asset acquisition accounting:

	Amount (in thousands)
Purchase price	$ 1,097,099
Less: net assets acquired	(1,153,026)
Remaining excess fair value of net assets acquired over the purchase price	**$ (55,927)**

Transaction costs of $20.7 million incurred by the Company to complete the EQRx Acquisition were accounted for as a direct reduction to the Company's additional paid-in capital, as these costs were primarily incurred to issue Revolution Medicines common stock as part of the capital-raising transaction.

In connection with the EQRx Acquisition, certain unvested outstanding stock options, restricted stock units and restricted stock awards of EQRx were accelerated and converted into the Company's common stock. As a result, the fair-value of the unvested portion of the accelerated EQRx equity awards of $11.2 million was recognized as a post-combination expense and included in stock-based compensation expense for the year ended December 31, 2023.

In connection with the EQRx Acquisition, as of the Closing Date, all public warrants of EQRx that were outstanding and unexercised immediately prior to the Closing Date were converted into 11,039,957 publicly traded warrants (Public Warrants) and 8,693,333 private placement warrants of the Company (Private Warrants and, together with the Public Warrants, the Warrants). Each Warrant entitles the holder to purchase 0.1112 shares of the Company's common stock, at an exercise price of $11.50 per such fractional share. The fair value of the Warrants on the Closing Date of $6.9 million was included in the purchase price. The Warrants expire in December 2026. The Public Warrants and Private Warrants met liability classification requirements because the Warrants contain provisions whereby adjustments to the settlement amount of the Warrants are based on a variable that is not an input to the fair value of a "fix-for-fixed" option and the existence of the potential for net cash settlement for the Warrant holders in the event of a tender offer. In addition, the Private Warrants are potentially subject to a different settlement amount depending upon the holder of the Private Warrants, which precludes them from being considered indexed to the entity's own stock. Therefore, the Warrants are classified as liabilities.

Prior to the EQRx Acquisition, holders of rights to EQRx earn-out shares held in escrow were entitled to receive additional shares of EQRx common stock for no consideration upon the occurrence of certain stock price-based triggering events (the earn-out shares). The earn-out shares were converted in the same manner as all other shares of EQRx common stock under the Merger Agreement and holders of rights to earn-out shares were entitled to receive up to 5,560,000 shares of common stock of the Company, subject to the triggering events. No triggering events occurred and the rights to the earn-out shares expired on December 17, 2024.

4. Fair value measurements

The following table presents information about the Company's financial assets that are measured at fair value and indicates the fair value hierarchy of the valuation:

	December 31, 2024			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets:				
Money market funds	$ 409,233	$ 409,233	$ —	$ —
Commercial paper	245,658	—	245,658	—
Certificates of deposit	9,048	—	9,048	—
U.S. government and agency securities	1,051,754	—	1,051,754	—
Corporate bonds	571,654	—	571,654	—
Total	$ 2,287,347	$ 409,233	$ 1,878,114	$ —
Liabilities:				
Warrant liabilities	3,189	1,784	1,405	—
Total	$ 3,189	$ 1,784	$ 1,405	$ —

	December 31, 2023			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets:				
Money market funds	$ 288,757	$ 288,757	$ —	$ —
Commercial paper	692,352	—	692,352	—
U.S. government and agency securities	786,406	—	786,406	—
Corporate bonds	85,218	—	85,218	—
Total	$ 1,852,733	$ 288,757	$ 1,563,976	$ —
Liabilities:				
Contingent earn-out liability	1,000	—	—	1,000
Warrant liabilities	6,512	3,643	2,869	—
Total	$ 7,512	$ 3,643	$ 2,869	$ 1,000

Money market funds are measured at fair value on a recurring basis using quoted prices. U.S. government debt securities, government agency bonds, certificates of deposit, commercial paper and corporate bonds are measured at fair value, which is derived from independent pricing sources based on quoted prices in active markets for similar securities.

There were no transfers between Levels 1, 2 or 3 for any of the periods presented.

The fair value of the warrant liabilities was based on observable listed prices for such warrants. The fair value of the public warrants is categorized as Level 1. The fair value of the private warrants is categorized as Level 2 as they are equivalent to the public warrants as they have substantially the same terms; however, they are not actively traded.

The contingent earn-out liability accounted for under ASC 815 is categorized as Level 3 fair value measurements within the fair value hierarchy because the Company estimates projections utilizing unobservable inputs.

5. Available-for-sale securities

The following tables summarize the amortized cost and estimated fair value of the Company's available-for-sale marketable securities and cash equivalents and the gross unrealized gains and losses:

	December 31, 2024			
	Amortized cost	Gross unrealized gain	Gross unrealized loss	Estimated fair value
	(in thousands)			
Marketable securities:				
Commercial paper	$ 158,838	$ 72	$ (17)	$ 158,893
Certificates of deposit	9,039	10	(1)	9,048
U.S. government and agency securities	1,011,019	1,123	(382)	1,011,760
Corporate bonds	566,008	657	(131)	566,534
Total marketable securities	1,744,904	1,862	(531)	1,746,235
Cash equivalents:				
Money market funds	409,233	—	—	409,233
Commercial paper	86,778	—	(13)	86,765
U.S. government and agency securities	39,991	4	(1)	39,994
Corporate bonds	5,120	—	—	5,120
Total cash equivalents	541,122	4	(14)	— 541,112
Total available-for-sale securities	$ 2,286,026	$ 1,866	$ (545)	$ 2,287,347

	December 31, 2023			
	Amortized cost	Gross unrealized gain	Gross unrealized loss	Estimated fair value
	(in thousands)			
Marketable securities:				
Commercial paper	$ 460,979	$ 108	$ (100)	$ 460,987
U.S. government and agency securities	610,188	769	(355)	610,602
Corporate bonds	85,030	189	(1)	85,218
Total marketable securities	1,156,197	1,066	(456)	1,156,807
Cash equivalents:				
Money market funds	288,757	—	—	288,757
Commercial paper	231,380	33	(48)	231,365
U.S. government and agency securities	175,855	3	(54)	175,804
Total cash equivalents	695,992	36	(102)	695,926
Total available-for-sale securities	$ 1,852,189	$ 1,102	$ (558)	$ 1,852,733

The amortized cost and estimated fair value of the Company's available-for-sale securities by contractual maturity are summarized below as of December 31, 2024:

	December 31, 2024			
	Amortized cost	Gross unrealized gain	Gross unrealized loss	Estimated fair value
	(in thousands)			
Mature in one year or less	$ 1,908,612	$ 1,805	$ (162)	$ 1,910,255
Mature after one year through two years	377,414	61	(383)	377,092
Total available-for-sale securities	$ 2,286,026	$ 1,866	$ (545)	$ 2,287,347

6. Balance sheet components

Property and equipment, net

Property and equipment, net consists of the following:

	December 31,	
	2024	2023
	(in thousands)	
Laboratory equipment	$ 25,192	$ 21,505
Leasehold improvements	14,280	11,952
Computer equipment and software	5,046	5,806
Furniture and fixtures	1,200	783
Construction in progress	394	513
	46,112	40,559
Less: accumulated depreciation and amortization	(21,823)	(17,694)
Property and equipment, net	$ 24,289	$ 22,865

Depreciation expense for property and equipment amounted to $6.2 million, $5.0 million and $4.0 million for the years ended December 31, 2024, 2023 and 2022, respectively.

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31,	
	2024	2023
	(in thousands)	
Accrued compensation	$ 30,774	$ 23,613
Accrued research and development	63,635	45,003
Accrued professional services	1,623	2,182
Other	583	3,896
Total accrued expenses and other current liabilities	$ 96,615	$ 74,694

7. Intangible assets and goodwill

Intangible assets, net

Intangible assets, net consist of the following as of December 31, 2024:

	Gross value	Accumulated amortization	Net book value	Weighted-average remaining useful life
		(in thousands)		(in years)
In-process research and development — RAS Programs	$ 55,800	$ —	$ 55,800	n/a
Developed technology — tri-complex platform	7,480	(6,610)	870	0.9
Total	$ 63,280	$ (6,610)	$ 56,670	

Amortization expense was $1.1 million for each of the years ended December 31, 2024, 2023 and 2022, respectively.

As of December 31, 2024, future amortization expense is as follows:

	Amount
	(in thousands)
2025	$ 870
Total	$ 870

Intangible assets, net consist of the following as of December 31, 2023:

	Gross value	Accumulated amortization	Net book value	Weighted-average remaining useful life
		(in thousands)		(in years)
In-process research and development — RAS Programs	$ 55,800	$ —	$ 55,800	n/a
Developed technology — tri-complex platform	7,480	(5,541)	1,939	1.9
Total	$ 63,280	$ (5,541)	$ 57,739	

Goodwill

The following summarizes the change in the carrying value of goodwill for the year ended December 31, 2024:

	Amount
	(in thousands)
Balance at December 31, 2023	$ 14,608
Adjustment	—
Balance at December 31, 2024	$ 14,608

No impairment has been recognized as of December 31, 2024. Goodwill recorded is not deductible for income tax purposes.

8. Commitments and contingencies

Leases

In January 2015, as amended in September 2016, the Company entered into an operating lease for approximately 42,000 square feet of office and laboratory space located at 700 Saginaw Drive, Redwood City, California (the 700 Building), with a term through April 2023. In April 2020, the Company amended the lease to lease an additional 19,000 square feet of office, laboratory and research and development space located at 300 Saginaw Drive, Redwood City, California (the 300 Building), and to extend the lease term through December 2030. In November 2021, the Company amended the lease to lease an additional 41,000 square feet of office, laboratory and research and development space located at 800 Saginaw Drive, Redwood City, California (the 800 Building), and to extend the lease term through November 2033. In March 2023, the Company amended the lease to lease an additional approximately 40,000 square feet of office, laboratory and research and development space located at 900 Saginaw Drive, Redwood City, California (the 900 Building), and to extend the lease term through December 31, 2035. The Company has the option to extend the lease for an additional ten years after December 31, 2035. The Company obtained possession of the 900 Building in October 2023. In July 2024, the Company amended its Redwood City lease to lease an additional approximately 43,000 square feet of office, laboratory and research and development space located at 500 Saginaw Drive, Redwood City, California (the 500 Building). The Company has the option to extend the lease for an additional ten years after the first anniversary of the lease commencement date of the 500 Building. In November 2024, the Company amended its Redwood City lease to lease an additional approximately 46,961 square feet of office, laboratory and research and development space located at 600 Saginaw Drive, Redwood City, California (the 600 Building). The Company has the option to extend the lease for an additional ten years after the first anniversary of the lease commencement date of the 600 Building. Additionally, in November 2024, the Company also entered into a sublease agreement pursuant to which approximately 23,481 square feet of office space located on the first floor of the 600 Building was subleased. The term of the sublease is through October 2027, with no options to extend. The sublease is accounted for as an operating lease.

The Company maintains letters of credit for the benefit of the landlord which are classified as restricted cash in the consolidated balance sheets. Restricted cash related to letters of credit due to the landlord was $3.7 million and $2.4 million as of December 31, 2024 and December 31, 2023, respectively.

Through December 31, 2024, the landlord had provided the Company with $16.3 million in tenant improvement allowances, which were recognized as lease incentives. The lease incentives are being amortized as an offset to rent expense over the lease term in the consolidated statements of operations and comprehensive loss.

Upon the execution of the lease amendment in March 2023, which was deemed to be a lease modification, the Company re-evaluated the assumptions used during the lease amendment in November 2021. The Company determined the amendment consists of two separate contracts under ASC 842. One contract is related to a new right-of-use asset for the 900 Building, which is being accounted for as an operating lease, and the other is related to the modification of the lease term, as amended in November 2021, for the 700 Building, 300 Building and 800 Building. As a result, the Company recorded a right-of-use asset and a lease liability of $25.0 million for the 900 Building and an aggregate increase of $0.3 million to the right-of-use assets and lease liabilities for the 700 Building, 300 Building and 800 Building upon execution of the lease amendment. The Company is recognizing rent expense for the buildings on a straight-line basis through the remaining extended term of the lease.

Upon the execution of the lease in July 2024, the Company determined that the contract is related to a new right-of-use asset for the 500 Building, which is being accounted for as an operating lease under ASC 842. Upon obtaining possession of the building in October 2024, the Company recorded a right-of-use asset of $18.2 million, a lease liability of $21.8 million and a lease receivable of $3.6 million for the 500 Building. The Company is recognizing rent expense for the buildings on a straight-line basis through the term of the lease.

Upon the execution of the lease in November 2024, the Company determined that the contract is related to a new right-of-use asset for the 600 Building, which is being accounted for as an operating lease under ASC 842. The Company recorded a right-of-use asset and a lease liability of $26.3 million for the 600 Building. The Company is recognizing rent expense for the buildings on a straight-line basis through the remaining extended term of the lease.

The balance sheet classification of the Company's operating lease liabilities was as follows:

	December 31, 2024
	(in thousands)
Operating lease liabilities:	
Operating lease liability – current	$ 12,872
Operating lease liability – noncurrent	122,971
Total operating lease liabilities	$ 135,843

The components of lease costs for the years ended December 31, 2024, 2023 and 2022 were as follows (in thousands):

	December 31,		
	2024	2023	2022
Operating lease cost	$ 12,166	$ 8,485	$ 8,854
Less: Sublease income	(561)	(302)	(2,476)
Total operating lease cost, net[(1)]	$ 11,605	$ 8,183	$ 6,378

(1) Net lease cost does not include short-term lease and variable lease costs, which were immaterial.

As of December 31, 2024, the maturities of the Company's operating lease liabilities were as follows (in thousands):

2025	$ 18,073
2026	17,048
2027	17,554
2028	17,695
2029	21,703
Thereafter	124,161
Total undiscounted lease payments	$ 216,234
Less: Imputed interest	(73,731)
Less: Lease receivable	(6,660)
Total operating lease liabilities	$ 135,843

Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company uses its incremental borrowing rate. The weighted-average discount rate used to determine the operating lease liability was 7.66%. As of December 31, 2024 and 2023, the weighted-average remaining lease term is 11.0 years and 12.0 years, respectively.

Legal matters

From time to time, the Company may become involved in litigation or other legal proceedings arising from the ordinary course of its business activities. Defending such proceedings is costly and can impose a significant burden on management and employees. The results of any current or future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors.

On December 9, 2024, *Nemeth v. Casdin, et al*., Case No. 2024-1268-KSJM (Del. Ch.), was filed in the Court of Chancery of the State of Delaware (the Complaint) arising from CM Life Sciences III., Inc.'s (CMLS III) December 17, 2021 merger with EQRx., Inc. (Legacy EQRx) (the Merger). The Complaint was filed by former stockholders of CMLS III and brings claims for breach of fiduciary duty and unjust enrichment against members of CMLS III's board of directors, CMLS III's officers, and CMLS III's sponsor in connection with the Merger. The Complaint also brings claims for aiding and abetting breaches of fiduciary duties against certain investment firms involved with the merger process, the Company, solely as successor-in-interest to EQRx, and Legacy EQRx's former Executive Chairman and CEO, Alexis Borisy, who is also on the Company's board of directors. Defendants' response to the Complaint is due on February 28, 2025.

At this juncture, the Company does not believe this action will have a material adverse impact on its operations or financial position. The Company is currently unable to predict the outcome of these lawsuits and therefore cannot determine the likelihood of loss, if any, nor estimate a range of possible loss.

Indemnification

The Company enters into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these arrangements is not determinable. The Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the fair value of these agreements is minimal.

Other

The Company enters into agreements in the ordinary course of business with contract research organizations for clinical trials, contract manufacturing organizations to provide clinical trial materials and with vendors for preclinical studies and other services and products for operating purposes which are generally cancelable at any time by the Company upon 30 to 90 days prior written notice.

9. Sanofi collaboration agreement

In June 2018, the Company entered into a collaborative research, development and commercialization agreement (the Sanofi Agreement) with Aventis, Inc. (an affiliate of Sanofi) to research and develop SHP2 inhibitors, including RMC-4630, for any indications. The Sanofi Agreement was assigned to Genzyme Corporation, a Sanofi affiliate, in December 2018. For the purposes of this discussion, the Company refers to Genzyme Corporation as Sanofi. The Sanofi Agreement was terminated in June 2023.

Pursuant to the Sanofi Agreement, the Company granted Sanofi a worldwide, exclusive, sublicensable (subject to the Company's consent in certain circumstances) license under certain of the Company's patents and know-how to research, develop, manufacture, use, sell, offer for sale, import and otherwise commercialize SHP2 inhibitors, including RMC-4630, for any and all uses, subject to the Company's exercise of rights and performance of obligations under the Sanofi Agreement.

Under the Sanofi Agreement, the Company had primary responsibility for early clinical development of RMC-4630 pursuant to an approved development plan. Sanofi was responsible for reimbursing the Company for all internal and external costs and expenses to perform its activities under approved development plans, except for costs and expenses related to the RMC-4630-03 study, for which Sanofi reimbursed the Company 50% of the costs and expenses.

Pursuant to the Sanofi Agreement, the Company received an upfront payment of $50 million from Sanofi in July 2018. The Sanofi Agreement included obligations for Sanofi to make certain milestone payments and royalty payments, all of which expired on termination of the Sanofi Agreement.

Upon termination of the Sanofi Agreement, the licenses granted to Sanofi thereunder became fully paid-up, royalty-free, perpetual and irrevocable and all rights and obligations of Sanofi under the Sanofi Agreement reverted to the Company.

During the years ended December 31, 2024, 2023 and 2022, the Company recognized zero, $11.6 million and $35.4 million of collaboration revenue associated with this agreement, respectively.

10. Common stock

As of December 31, 2024 and 2023, the Company's certificate of incorporation authorized the Company to issue 300,000,000 shares of common stock, at a par value of $0.0001 per share. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors. As of December 31, 2024, no dividends have been declared to date.

The Company evaluated the pre-funded warrants issued in conjunction with the December 2024 underwritten public offering and concluded that they met the criteria to be classified as equity within additional paid-in-capital. The pre-funded warrants have been classified as equity because they (1) are freestanding financial instruments that are legally detachable and separately exercisable from the common stock, (2) are immediately exercisable, (3) do not embody an obligation for the Company to repurchase its shares, (4) permit the holder to receive a fixed number of shares of common stock upon exercise, (5) are indexed to the Company's common stock and (6) meet the equity classification criteria. All of the shares underlying the pre-funded warrants have been included in the weighted-average number of shares of common stock used to calculate net loss per share attributable to common stockholders because the shares may be issued for little or no consideration, are fully vested and are exercisable after the original issuance date of the pre-funded warrants.

The Company has reserved shares of common stock for future issuance as follows:

	December 31, 2024	December 31, 2023
Outstanding options to purchase common stock	13,985,538	11,083,349
Unvested restricted stock units of common stock	2,850,112	2,161,267
Available for future issuance under the 2020 Incentive Award Plan	8,945,644	6,241,188
Available for issuance under the 2020 Employee Stock Purchase Plan	3,775,682	2,394,407
Pre-funded warrants issued and outstanding	2,173,917	—
Total common stock reserved for future issuance	31,730,893	21,880,211

11. Stock-based compensation

2020 Incentive Award Plan

In February 2020, the Company adopted the 2020 Equity Incentive Plan (the 2020 Plan). The 2020 Plan became effective on February 11, 2020. The 2020 Plan provides for a variety of stock-based compensation awards, including stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance bonus awards, performance stock unit awards, dividend equivalents, or other stock or cash based awards. Under the 2020 Plan, the Company generally grants stock-based awards with service-based vesting conditions only. Options and restricted stock unit awards granted typically vest over a four-year period, but may be granted with different vesting terms.

Following the effectiveness of the 2020 Plan, the Company ceased making grants under the 2014 Equity Incentive Plan (the 2014 Plan). However, the 2014 Plan continues to govern the terms and conditions of the outstanding awards granted under it. Shares of common stock subject to awards granted under the 2014 Plan that are forfeited or lapse unexercised and which following the effective date of the 2020 Plan were not issued under the 2014 Plan are available for issuance under the 2020 Plan.

2020 Employee Stock Purchase Plan

In February 2020, the Company adopted the 2020 Employee Stock Purchase Plan (the ESPP). Under the ESPP, employees have the ability to purchase shares of the Company's common stock through payroll deductions at a discount during a series of offering periods of 24 months, each comprised of four six-month purchase periods. The purchase price will be the lower of 85% of the closing trading price per share of the Company's common stock on the first day of an offering period in which an employee is enrolled or 85% of the closing trading price per share on the purchase date, which will occur on the last trading day of each purchase period.

As of December 31, 2024, there have been 265,470 shares of common stock purchased under the ESPP. As of December 31, 2024, a total of 3,775,682 shares of common stock were available for future issuance under the ESPP. As of December 31, 2024, there was $4.9 million of unrecognized compensation cost related to the ESPP.

Stock options

The following summarizes option activity under both the 2020 Plan and the 2014 Plan:

	Number of Shares underlying options	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Balance, December 31, 2023	11,083,349	$ 19.64	7.50	$ 115,009
Options granted	4,170,607	34.23		
Options exercised	(927,275)	13.30		
Options cancelled and forfeited	(341,143)	26.46		
Balance, December 31, 2024	13,985,538	$ 24.25	7.36	$ 276,335
Options vested and exercisable as of December 31, 2024	7,629,736	$ 19.04	6.22	$ 188,535

The aggregate intrinsic values of options outstanding, exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock by the Board of Directors. The intrinsic value of the options exercised for the years December 31, 2024, 2023 and 2022 was $29.4 million, $10.7 million and $3.8 million, respectively.

During the years ended December 31, 2024, 2023 and 2022, the weighted-average grant-date fair value of options granted was $22.07, $17.82 and $12.33 per share, respectively. As of December 31, 2024, there was $118.8 million of unrecognized stock-based compensation expense related to unvested stock options that is expected to be recognized over a weighted-average period of 2.65 years.

The fair value of employee and director stock option awards was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2024	2023	2022
Expected term (years)	6	6	6
Expected volatility	67%-68%	73-75%	70-73%
Risk-free interest rate	3.6%-4.6%	3.5%-4.7%	1.5%-4.2%
Dividend yield	0%	0%	0%

The Black-Scholes model assumptions that determine the fair value of stock-based awards include:

Expected term—The expected term is calculated using the simplified method, which is available where there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method.

Expected volatility—Given the Company does not have sufficient trading history for its common stock, the expected volatility was estimated based on the average volatility of the Company and comparable publicly traded biotechnology companies over a period

equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Expected dividend—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

Restricted stock units

Restricted stock units (RSUs) have been granted to employees and directors. The fair value of an RSU award is based on the Company's stock price on the date of grant. The shares underlying the RSU awards are not issued until the RSUs vest. Upon vesting, each RSU converts into one share of the Company's common stock. The Company has granted RSUs pursuant to the 2020 plan.

Activity under the 2020 Plan with respect to the Company's RSUs during the year ended December 31, 2024 was as follows:

	Number of Shares	Weighted-average grant date fair value per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Balance, December 31, 2023	2,161,267	$ 25.10	1.56	$ 61,985
RSUs granted	1,873,085	34.77		
RSUs vested	(1,011,255)	26.48		
RSUs forfeited	(172,985)	26.81		
Balance, December 31, 2024	2,850,112	$ 30.87	1.49	$ 124,664
Expected to vest as of December 31, 2024	2,850,112	$ 30.87	1.49	$ 124,664

The number of RSUs vested includes shares of common stock that the Company withheld to satisfy the minimum statutory tax withholding requirements. As of December 31, 2024, there was $82.9 million of total unrecognized compensation cost related to RSUs that is expected to be recognized over a weighted average period of 2.79 years.

The total grant date fair value of RSUs vested for the years ended December 31, 2024, 2023 and 2022 was $26.8 million, $14.3 million and $7.9 million, respectively.

Stock-based compensation expense

Total stock-based compensation expense related to stock options, RSUs and the ESPP by function was as follows:

	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Research and development	$ 50,973	$ 34,126	$ 18,113
General and administrative	28,224	27,646	13,083
Total	$ 79,197	$ 61,772	$ 31,196

In connection with the EQRx Acquisition, certain unvested outstanding stock options, restricted stock units and restricted stock awards of EQRx were accelerated and converted into the Company's common stock. The fair-value of the unvested portion of the accelerated EQRx equity awards of $11.2 million (of which $3.7 million was attributed to employees working on research and development projects and $7.5 million working on general and administration) was recognized as a post-combination expense and included in stock-based compensation expense for the year ended December 31, 2023.

12. Income taxes

The Company's income (loss) before provision for income taxes for the years ended December 31, 2024, 2023 and 2022 consist of the following:

	December 31,		
	2024	2023	2022
	(in thousands)		
Domestic	$ (600,849)	$ (440,683)	$ (249,125)
International	(50)	792	—
Income (loss) before provision for income taxes	$ (600,899)	$ (439,891)	$ (249,125)

The components of the provision for income taxes for the years ended December 31, 2024, 2023 and 2022 consist of the following:

	December 31,		
	2024	2023	2022
	(in thousands)		
Current:			
Federal	$ —	$ —	$ —
State	27	112	—
Foreign	(42)	212	—
Total current	(15)	324	—
Deferred:			
Federal	—	—	—
State	(721)	(3,865)	(420)
Foreign	(17)	17	—
Total deferred	(738)	(3,848)	(420)
Benefit for income taxes	$ (753)	$ (3,524)	$ (420)

The Company recorded an income tax benefit of $0.8 million, $3.5 million and $0.4 million for the years ended December 31, 2024, 2023 and 2022, respectively, which reflects a blended state tax rate applied to the indefinite lived intangibles recorded as part of the Company's acquisition of Warp Drive Bio in 2018. The Company has incurred net pre-tax losses in the United States for all periods presented. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the carrying amounts of existing assets and liabilities in the financial statements and their respective tax bases using tax rates expected to be in effect during the years in which the basis differences reverse.

The benefit from income taxes differs from the amount expected by applying the federal statutory rate to the loss before taxes as follows:

	Year Ended December 31,		
	2024	2023	2022
Federal statutory income tax rate	21.0%	21.0%	21.0%
State income tax rate, net of federal benefit	5.2%	-2.3%	9.4%
Foreign rate differential	0.0%	0.0%	0.0%
Research tax credits	4.7%	2.7%	3.2%
Change in valuation allowance	-31.1%	-19.8%	-32.4%
Permanent tax differences	0.1%	0.1%	-0.1%
Stock based compensation	-0.2%	-0.8%	-0.9%
Other	0.4%	-0.1%	0.0%
Benefit from income taxes	0.1%	0.8%	0.2%

Deferred income tax reflects the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The categories that give rise to significant components of the deferred tax assets are as follows (in thousands):

	December 31,	
	2024	2023
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 226,501	$ 147,576
Accruals and reserves	9,951	5,747
Research and development credits	66,001	34,755
Lease liability	37,477	19,628
Stock-based compensation	20,215	9,872
Capitalized research expenses	247,725	185,909
Other	1,140	161
Gross deferred tax assets	609,010	403,648
Less: valuation allowance	(563,912)	(376,762)
Total deferred tax assets	45,098	26,886
Deferred tax liabilities:		
Fixed assets and finite-lived intangible assets	(12,671)	(9,683)
Indefinite-lived intangible assets	(2,354)	(3,099)
Right-of-use asset	(32,426)	(17,219)
Gross deferred tax liabilities	(47,451)	(30,001)
Net deferred tax liability	$ (2,353)	$ (3,115)

The realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Due to the lack of earnings history, the net deferred tax assets have been offset by a valuation allowance excluding certain indefinite lived intangibles. The valuation allowance increased by $187.2 million, $152.6 million and $80.7 million during the years ended December 31, 2024, 2023 and 2022, respectively. The Company had federal and state net operating loss carryforwards of $151.8 million and $74.7 million, respectively, as presented in the table above, as of December 31, 2024. The federal net operating loss carryforwards, if not utilized, will expire beginning in 2035, with the exception of $132.2 million in federal net operating loss carryforwards, which can be carried forward indefinitely. State net operating loss carryforwards, if not utilized, will expire beginning in 2035. Under the Tax Cuts and Jobs Act (TCJA), federal net operating losses arising after December 31, 2017 do not expire and cannot be carried back. However, the TCJA limits the amount of federal net operating losses that can be used annually to 80% of taxable income for periods beginning after December 31, 2017. Existing federal net operating losses arising in years ending on or before December 31, 2017 are not affected by these provisions.

The Company also had federal and state research and development credit carryforwards of $48.2 million and $17.8 million, respectively, as of December 31, 2024. The federal research credits will expire beginning in 2034 if not utilized and the state research credits will expire beginning in 2031, with the exception of $16.8 million in California research credits, which can be carried forward indefinitely. Federal and state tax laws impose significant restrictions on the utilization of net operating loss carryforwards in the event of a change in ownership of the Company, as defined by Internal Revenue Code Section 382 (Section 382). The Company performed a study in which it determined that it had experienced changes in ownership in 2014, 2020 and 2023 as defined by Section 382. The Company's deferred tax assets have been reduced by the amount of net operating loss carryforwards expected to expire due to the limitation. In addition, in the future the Company may experience ownership changes, which may limit the utilization of net operating loss carryforwards or other tax attributes.

The TCJA amended Internal Revenue Code Section 174 requiring capitalization of specified research and experimental expenditures paid or incurred in tax years beginning after December 31, 2021 and amortizing over a period of 5 or 15 years. This resulted in a deferred tax asset for capitalized research expenses in 2024, 2023 and 2022.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

	December 31,		
	2024	2023	2022
	(in thousands)		
Beginning balance	$ 191,407	$ 7,602	$ 5,143
Changes related to tax positions taken in the prior year	3,226	155,178	(7)
Changes related to tax positions taken in the current year	11,567	28,627	2,466
Ending balance	$ 206,200	$ 191,407	$ 7,602

The Company has unrecognized tax benefits of $198.1 million, $184.2 million and $7.1 million as of December 31, 2024, 2023 and 2022 which would affect the effective tax rate if recognized; however, recognition would be in the form of a deferred tax attribute which would likely be offset by a valuation allowance. The Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months. The Company has recognized no interest or penalties related to uncertain tax positions for the periods presented.

Income tax returns are filed in the United States. The years 2010 through 2024 remain open to examination by the domestic taxing jurisdictions to which the Company is subject. Net operating losses generated on a tax return basis by the Company for 2010 through 2024 remain open to examination by the domestic taxing jurisdictions.

13. Net loss per share attributable to common stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders:

	Years Ended December 31,		
	2024	2023	2022
	(in thousands, except share and per share data)		
Numerator:			
Net loss	$ (600,093)	$ (436,367)	$ (248,705)
Redeemable convertible preferred stock dividends-undeclared and cumulative	—	—	—
Net loss attributable to common stockholders	$ (600,093)	$ (436,367)	$ (248,705)
Denominator:			
Weighted-average shares outstanding	167,737,672	113,149,869	80,636,570
Less: Weighted-average unvested restricted shares and shares subject to repurchase	—	—	(10,045)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	167,737,672	113,149,869	80,626,525
Net loss per share attributable to common stockholders, basic and diluted	$ (3.58)	$ (3.86)	$ (3.08)

The shares underlying the pre-funded warrants to purchase shares of the Company's common stock have been included in the calculation of the weighted-average number of shares outstanding, basic and diluted, for the years ended December 31, 2024 and 2023.

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	As of December 31,		
	2024	2023	2022
Options to purchase common stock	13,985,538	11,083,349	8,164,375
Options early exercised subject to future vesting	—	—	6,918
Unvested restricted stock units of common stock	2,850,112	2,161,267	1,175,032
Expected shares to be purchased under ESPP	400,353	230,651	378,429
Warrants outstanding	2,194,342	2,194,342	—
Earn-out shares	—	973,976	—
Total	19,430,345	16,643,585	9,724,754

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

None.

Item 9A. Controls and Procedures.

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, our principal executive officer and principal financial officer, respectively, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2024. Based on the evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of December 31, 2024, our disclosure controls and procedures were effective.

Management's annual 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 Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of our internal control over financial reporting based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our evaluation, management has concluded that our internal control over financial reporting was effective at the reasonable assurance level as of December 31, 2024.

The effectiveness of our internal control over financial reporting as of December 31, 2024 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Changes in internal control over financial reporting

There were no changes in our internal controls over financial reporting during the three months ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness over financial reporting

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, 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. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

Item 9B. Other Information.

Rule 10b5-1 Plans

During the three months ended December 31, 2024, the following directors and officers of the Company adopted Rule 10b5-1 trading arrangements intended to satisfy the affirmative defense of Rule 10b5-1(c) promulgated under the Exchange Act. The details of these arrangements are as follows:

On December 16, 2024, Jack Anders, our Chief Financial Officer, adopted a Rule 10b5-1 trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) promulgated under the Exchange Act, which provides for the potential exercise and sale of up to 35,418 shares of our common stock subject to a stock option held by Mr. Anders. The trading plan will terminate at the earlier of the execution of all trading orders pursuant to the plan and March 13, 2026.

On December 19, 2024, Mark A. Goldsmith, M.D., Ph.D., our President and Chief Executive Officer and Chair of the Board of Directors, adopted a Rule 10b5-1 trading plan. Dr. Goldsmith's Rule 10b5-1 trading plan is intended to satisfy the affirmative defense

conditions of Rule 10b5-1(c) promulgated under the Exchange Act, and provides for (i) the potential exercise and sale of up to 150,000 shares of our common stock subject to a stock option held by Dr. Goldsmith, (ii) the potential sale of up to 3,000 shares of our common stock by a trust for which Dr. Goldsmith is a trustee and (iii) the potential sale of up to 3,000 shares of our common stock by a trust for which Dr. Goldsmith is a trustee. The trading plan will terminate at the earlier of the execution of all trading orders pursuant to the plan and March 31, 2026.

On December 23, 2024, Wei Lin, M.D., our Chief Medical Officer, adopted a Rule 10b5-1 trading arrangement intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) promulgated under the Exchange Act. Dr. Lin's trading arrangement covers the sale of the number of shares of our common stock required to be sold to cover tax withholding obligations for restricted stock unit awards that vest after March 15, 2025. The aggregate number of shares to be sold pursuant to this trading arrangement is dependent on the number of restricted stock units awards that may be granted to Dr. Lin from time to time and the taxes on these restricted stock unit awards, and, therefore, is indeterminable at this time.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2024, and is incorporated herein by reference.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees, which is available on our website at ir.revmed.com/. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Insider Trading Compliance Policy and Guidelines

We have adopted an insider trading compliance policy and procedures governing the purchase, sale and other dispositions of our securities by our directors, officers, employees and certain contractors and consultants that are designed to promote compliance with insider trading laws, rules and regulations, and applicable Nasdaq listing standards, as well as procedures designed to further the foregoing purposes. A copy of our insider trading policy is filed with this Annual Report on Form 10-K as Exhibit 19.1.

Item 11. Executive Compensation.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A to be filed within 120 days after December 31, 2024, and is incorporated herein by reference.

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

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A to be filed within 120 days after December 31, 2024, and is incorporated herein by reference.

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

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A to be filed within 120 days after December 31, 2024, and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A to be filed within 120 days after December 31, 2024, and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements:

The following financial statements and schedules of the Registrant are contained in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K:

2. Financial Statement Schedules

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or notes thereto.

(b) Exhibits

The exhibits listed in the following "Exhibit Index" are filed, furnished or incorporated by reference as part of this Annual Report.

Exhibit Index

Exhibit number	Exhibit description	Incorporated by reference			Filed herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation.	8-K	2/18/2020	3.1	
3.2	Amended and Restated Bylaws.	8-K	3/8/2021	3.1	
4.1	Reference is made to Exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate.	S-1	1/17/2020	4.2	
4.3	Description of Securities.				X
4.4(a)	Warrant Agreement, dated April 6, 2021, by and between Continental Stock Transfer & Trust Company and EQRx, Inc.	10-K	2/26/2024	4.4(a)	
4.4(b)	Appointment, Assignment and Assumption Agreement, dated November 9, 2023, by and among EQRx, Inc., Revolution Medicines, Inc., Continental Stock Transfer & Trust Company and Equiniti Trust Company, LLC.	8-A	11/15/2023	4.2(b)	
4.5	Form of Pre-Funded Warrant	8-K	12/5/2024	4.1	
10.1A†	Collaborative Research, Development and Commercialization Agreement, dated as of June 8, 2018, by and between Revolution Medicines, Inc. and Aventis, Inc., as amended.	S-1	1/17/2020	10.1	
10.1B†	Letter Agreement and Amendment, dated as of August 5, 2021 by and between Revolution Medicines, Inc. and Genzyme Corporation.	10-Q	8/11/2021	10.2	
10.2A	Lease between HCP LS Redwood City, LLC and Revolution Medicines, Inc., dated as of January 15, 2015.	S-1	1/17/2020	10.3A	
10.2B	First Amendment to Lease by and between HCP LS Redwood City, LLC and Revolution Medicines, Inc., dated as of September 16, 2016.	S-1	1/17/2020	10.3B	
10.2C	Sublease between OncoMed Pharmaceuticals, Inc. and Revolution Medicines, Inc., dated as of January 16, 2019.	S-1	1/17/2020	10.3C	
10.2D	Second Amendment to Lease by and between HCP LS Redwood City, LLC and Revolution Medicines, Inc., dated as of April 17, 2020.	10-Q	5/14/2020	10.4	
10.2E	Third Amendment to Lease by and between HCP LS Redwood City, LLC and Revolution Medicines, Inc., dated as of November 1, 2021.	10-Q	11/10/2021	10.1	
10.2F	Fourth Amendment to Lease and between HCP LS Redwood City, LLC and Revolution Medicines, Inc., dated as of March 24, 2023	10-Q	5/8/2023	10.2	
10.2G	Fifth Amendment to Lease and between HCP LS Redwood City, LLC and Revolution Medicines, Inc., dated as of August 3, 2023	10-Q	11/6/2023	10.3	
10.2H	Sixth Amendment, dated as of July 12, 2024, to Lease by and between HCP LS Redwood City, LLC and Revolution Medicines, Inc.	10-Q	11/6/2024	10.1	
10.2I	Seventh Amendment, dated as of November 5, 2024, to Lease by and between HCP LS Redwood City, LLC and Revolution Medicines, Inc.				X
10.2J	Sublease between Editco Bio Inc. and Revolution Medicines, Inc., dated as of November 5, 2024				X
10.3(a)#	2014 Equity Incentive Plan, as amended.	S-1	1/17/2020	10.6(a)	
10.3(b)#	Form of Amended and Restated Early Exercise Stock Option Grant Notice and Amended and Restated Stock Option Agreement under 2014 Equity Incentive Plan, as amended.	S-1	1/17/2020	10.6(b)	

Exhibit number	Exhibit description	Incorporated by reference			Filed herewith
		Form	Date	Number	
10.4(a)#	2020 Incentive Award Plan.	S-1/A	2/3/2020	10.7(a)	
10.4(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2020 Incentive Award Plan.	S-1/A	2/3/2020	10.7(b)	
10.4(c)#	Form of Restricted Stock Award Agreement under the 2020 Incentive Award Plan.	S-1/A	2/3/2020	10.7(c)	
10.4(d)#	Form of Restricted Stock Unit Award Grant Notice under the 2020 Incentive Award Plan.	S-1/A	2/3/2020	10.7(d)	
10.5#	2020 Employee Stock Purchase Plan.	S-1/A	2/3/2020	10.8	
10.6A#	Employment Agreement by and between Revolution Medicines, Inc. and Mark A. Goldsmith, M.D., Ph.D.	S-1	1/17/2020	10.9	
10.6B#	First Amendment to Employment Agreement dated June 10, 2022 by and between Revolution Medicines, Inc. and Mark Goldsmith, M.D., Ph.D.	8-K	06/10/2022	10.1	
10.7#	Employment Agreement by and between Revolution Medicines, Inc. and Steve Kelsey, M.D., FRCP, FRCPath.	S-1	1/17/2020	10.10	
10.8#	Employment Agreement by and between Revolution Medicines, Inc. and Margaret Horn, J.D.	S-1	1/17/2020	10.11	
10.9#	Non-Employee Director Compensation Program.	10-Q	05/08/2024	10.1	
10.10#	Form of Indemnification Agreement for directors and officers.	S-1/A	2/3/2020	10.13	
10.11#	Employment Agreement, dated as of August 1, 2024 by and between Revolution Medicines, Inc. and Jack Anders.	10-Q	08/07/2024	10.2	
10.12#	Employment Agreement dated as of August 1, 2024 by and between Revolution Medicines, Inc. and Xiaolin Wang, Sc.D.	10-Q	08/07/2024	10.3	
19.1^	Insider Trading Compliance Policy and Procedures				X
21.1	Subsidiaries of Registrant.				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney (included on signature page to this Form 10-K).				X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
97	Policy for Recovery of Erroneously Awarded Compensation	10-K	02/26/2024	97	
101.INS	Inline XBRL Instance Document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbases Document.				X

Exhibit number	Exhibit description	Incorporated by reference			Filed herewith
		Form	Date	Number	
104	The cover page from Revolution Medicines, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2024, formatted in Inline XBRL and contained in Exhibit 101.				X

† Portions of the exhibit, marked by brackets, have been omitted because the omitted information (i) is not material and (ii) is the type of information that Revolution Medicines, Inc. treats as private or confidential.

^ Portions of this exhibit have been omitted in accordance with Item 601(a)(5) of Regulation S-K. Revolution Medicines, Inc. undertakes to furnish a copy of all omitted schedules and exhibits to the Securities and Exchange Commission upon its request.

# Indicates management contract or compensatory plan.

* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Revolution Medicines, 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 Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

Revolution Medicines, Inc.

Date: February 26, 2025

By: /s/ Mark A. Goldsmith
Mark A. Goldsmith, M.D., Ph.D.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Mark A. Goldsmith, M.D., Ph.D., Jack Anders and Jeff Cislini and each of them acting individually, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution, for him in any and all capacities, to sign 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 attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof

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

Name	Title	Date
/s/ Mark A. Goldsmith Mark A. Goldsmith, M.D., Ph.D.	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 26, 2025
/s/ Jack Anders Jack Anders	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 26, 2025
/s/ Elizabeth McKee Anderson Elizabeth McKee Anderson	Director	February 26, 2025
/s/ Flavia Borellini Flavia Borellini, Ph.D.	Director	February 26, 2025
/s/ Alexis Borisy Alexis Borisy	Director	February 26, 2025
/s/ Frank Clyburn Frank Clyburn	Director	February 26, 2025
/s/ Sandra Horning Sandra J. Horning, M.D.	Director	February 26, 2025
/s/ Lorence Kim Lorence Kim, M.D.	Director	February 26, 2025
/s/ Sushil Patel Sushil Patel, Ph.D.	Director	February 26, 2025
/s/ Thilo Schroeder Thilo Schroeder, Ph.D.	Director	February 26, 2025
/s/ Barbara Weber Barbara Weber, M.D.	Director	February 26, 2025

REVOLUTION MEDICINES, INC. CORPORATE INFORMATION

BOARD OF DIRECTORS

Mark A. Goldsmith, M.D., Ph.D.
President, Chief Executive Officer and Chair of the Board

Elizabeth McKee Anderson
Former Worldwide Vice President, Commercial Leader, Infectious Diseases and Vaccines of Janssen Pharmaceuticals, Inc.

Flavia Borellini, Ph.D.
Former Global Franchise Head, Hematology of AstraZeneca PLC

Alexis Borisy
Director at Nextech Invest Ltd. and Co-founder of Curie.Bio

Frank K. Clyburn, Jr.
Former Executive Vice President and Division President of Human Health at Merck & Co., Inc.

Sandra Horning, M.D.
Former Chief Medical Officer and Global Head of Product Development at Roche/Genentech

Lorence Kim, M.D.
Co-founder and Managing Partner of Ascenta Capital Management, LLC

Sushil Patel, Ph.D.
Chief Executive Officer of Replimune Group, Inc.

Thilo Schroeder, Ph.D.
Managing Partner at Nextech Invest Ltd.

Barbara Weber, M.D.
President and Chief Executive Officer of Tango Therapeutics, Inc.

EXECUTIVE OFFICERS

Mark A. Goldsmith, M.D., Ph.D.
President, Chief Executive Officer and Chair of the Board

Jack Anders
Chief Financial Officer

Steve Kelsey, M.D., FRCP, FRCPath
President, Research and Development

Margaret Horn, J.D.
Chief Operating Officer

Wei Lin, M.D.
Chief Medical Officer

Xiaolin Wang, Sc.D.
Executive Vice President, Development

Jeff Cislini
Senior Vice President, General Counsel and Secretary

STOCKHOLDER ACCOUNT ASSISTANCE

Registered stockholder records are maintained by our transfer agent:

Equiniti Trust Company, LLC
Attn: Shareholder Services
P.O. Box 500
Newark, NJ 07101
Toll-free telephone number is open Monday - Friday 8 a.m. to 8 p.m. ET
U.S. only: (800) 937-5449
International: (718) 921-8124
Website: equiniti.com/us
E-mail: HelpAST@equiniti.com

FINANCIAL INFORMATION

Copies of Revolution Medicines, Inc.'s periodic reports and proxy statements are available on the Company's website.

ANNUAL MEETING OF STOCKHOLDERS

The annual meeting of stockholders of Revolution Medicines, Inc. will be held on June 26, 2025 at 7:30 a.m. Pacific Time, via live webcast at www.virtualshareholdermeeting.com/RVMD2025.

STOCK LISTING

The Nasdaq Global Select Market
Nasdaq Symbol: RVMD