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, 2020

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: 001-39385

RELAY THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**47-3923475**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
399 Binney Street, 2nd Floor Cambridge, MA	**02139**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 370-8837

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**RLAY**	**Nasdaq Global Market**

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

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 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. ☐

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 Registrant's common stock held by non-affiliates of the Registrant was $2,543,277,454 as of the closing of the Registrant's initial public offering on July 20, 2020 (based on a closing price of $42.87 per share as quoted by the Nasdaq Global Market as of such date). In determining the market value of non-affiliate common stock, shares of the Registrant's common stock beneficially owned by officers, directors and affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's Common Stock outstanding as of March 23, 2021 was 90,399,972.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A relating to the 2021 Annual Meeting of Stockholders within 120 days of the end of the registrant's fiscal year ended December 31, 2020. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

- We have never successfully completed any clinical trials, and we may be unable to do so for any product candidates we develop. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- Positive results from early preclinical studies of our product candidates are not necessarily predictive of the results of later preclinical studies and any future clinical trials of our product candidates. If we cannot replicate the positive results from our earlier preclinical studies of our product candidates in our later preclinical studies and future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.
- Our current or future clinical trials may reveal significant adverse events not seen in our preclinical or nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.
- Although we intend to explore other therapeutic opportunities, in addition to the product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.
- The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.
- Under our Amended and Restated Collaboration and License Agreement, or the DESRES Agreement, with D. E. Shaw Research, LLC, or D. E. Shaw Research, we collaborate with D. E. Shaw Research to rapidly develop various protein models, a process that depends on D. E. Shaw Research's use of their proprietary supercomputer, Anton 2. A termination of the DESRES Agreement could have a material adverse effect on our business, financial condition, results of operations, and prospects.
- We rely on third parties to conduct our ongoing clinical trials of RLY-1971 and RLY-4008 and expect to rely on third parties to conduct future clinical trials, as well as investigator-sponsored clinical trials of 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 regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- We may enter into collaborations with third parties for the research, development, manufacture and commercialization of one or more of our programs or product candidates. If these collaborations are not successful, our business could be adversely affected.
- We are a biopharmaceutical company with a limited operating history. We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future. We have no products approved for commercial sale and have not generated any revenue from product sales.
- We will need to raise substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate some of our product development programs or commercialization efforts.

- A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.
- If we are unable to adequately protect our proprietary technology or obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.
- Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.
- We are an “emerging growth company” as defined in the JOBS Act and a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, and may avail ourselves of reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical and clinical studies, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to identify research priorities and apply a risk-mitigated strategy to efficiently discover and develop product candidates, including by applying learnings from one program to other programs and from one modality to our other modalities;
- our ability and the potential to successfully manufacture our drug substances, delivery vehicles, and product candidates for preclinical use, for clinical trials and on a larger scale for commercial use, if approved;
- the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and product candidates;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to commercialize our products, if approved;
- 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;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- estimates of our future expenses, revenues, capital requirements, and our needs for additional financing;
- the potential benefits of strategic collaboration agreements, our ability to enter into strategic collaborations or arrangements, and our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the commercialization of product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our financial performance;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to produce our products or product candidates with advantages in turnaround times or manufacturing cost;

- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the impact of laws and regulations;
- developments relating to our competitors and our industry;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies and future clinical trials; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

In some cases, you can identify forward-looking statements by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed above under “Summary of the Material Risks Associated with Our Business” and under the section titled “Risk Factors” and elsewhere in this Annual Report on Form 10-K. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K and have filed with the Securities and Exchange Commission, or the SEC, as exhibits hereto completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this Annual Report on Form 10-K, their estimates, in particular as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties and are subject to change based on various factors, including those discussed under the section titled “Risk Factors” and elsewhere in this Annual Report on Form 10-K.

PART I

Except where the context otherwise requires or where otherwise indicated, the terms "Relay Therapeutics," "we," "us," "our," "our company," the "Company," and "our business" refer to Relay Therapeutics, Inc. and its consolidated subsidiary.

Item 1. Business.

Overview

We are a clinical-stage precision medicines company transforming the drug discovery process with an initial focus on enhancing small molecule therapeutic discovery in targeted oncology. Our company is built upon unparalleled insights into protein motion and how this dynamic behavior relates to protein function. These insights may enable us to more effectively drug protein targets that previously have been intractable (i.e., inadequately drugged or undruggable). We believe we have a differentiated approach to drug these protein targets based on their motion, which enables us to select and advance unique product candidates. We built our Dynamo™ platform to integrate an array of leading edge experimental and computational approaches, which allows us to apply our understanding of protein structure and motion to drug discovery.

We are advancing a pipeline of medicines to address targets in precision oncology, including our lead product candidates, RLY-1971 and RLY-4008, as well as our PI3Kα mutant selective program, or the RLY-PI3K1047 program. We initiated a Phase 1 clinical trial for RLY-1971, our inhibitor of Src homology region 2 domain-containing phosphatase-2, or SHP2, in patients with advanced solid tumors in the first quarter of 2020. In December 2020, we entered into a global collaboration and license agreement, or the Genentech Agreement, with Genentech, Inc., a member of the Roche Group, or Genentech, for the development and commercialization of RLY-1971. We initiated a first-in-human clinical trial of RLY-4008, our inhibitor of fibroblast growth factor receptor 2, or FGFR2, enriched for patients with advanced solid tumors having oncogenic FGFR2 alterations in the third quarter of 2020. We anticipate the RLY-PI3K1047 program, our program for molecules targeting cancer-associated mutant variants of phosphoinostide 3-kinase alpha, or PI3Kα, to be in Investigational New Drug, or IND, enabling studies in 2021. While our initial focus is on precision oncology, we believe our Dynamo platform may also be broadly applied to other areas of precision medicine, such as genetic disease. In addition to the three product candidates described above, we have five discovery stage programs across precision oncology and genetic disease. We are focused on using the novel insights derived from our approach to transform the lives of patients suffering from debilitating and life-threatening diseases through the discovery, development and commercialization of our therapies.

Precision medicine emerged as an approach for disease treatment as the understanding of the link between genetic alterations, protein dysfunction and diseases evolved. Precision medicine aims to specifically and potently drug genetically validated target proteins (i.e., genetic variants potentially implicated in biology of disease). However, some target proteins thus far have been intractable using conventional drug discovery tools, such as structure-based drug design, or SBDD. While SBDD is well-suited to solving some drug discovery problems such as orthosteric site kinase inhibitors, its reliance on static images of protein fragments limits its ability to gain accurate insights into the dynamic behavior of proteins in their natural state, which in turn limits its ability to discover medicines with exquisite specificity. Our approach pivots the understanding of protein targets from the industry-standard, static view, to a novel paradigm based on fundamental insights into protein motion. We then apply these novel insights into protein motion to drug discovery and design, which we term Motion Based Drug Design™, or MBDD.

The confluence of three forces — the proliferation of readily available genomic data, the evolution of experimental techniques, and advancements in computational power and speed — led to the founding of Relay Therapeutics. We believe we are uniquely situated in our ability to consolidate these advances and, when combined with our world-class team of both experimental and computational experts, integrate these solutions into MBDD to create medicines that will make a transformative difference for patients.

Key Drug Discovery Steps of Our Dynamo Platform

Our Dynamo platform puts protein motion at the center of drug discovery and design, integrating a broad and tailored array of leading-edge experimental and computational approaches, including deploying the Anton 2

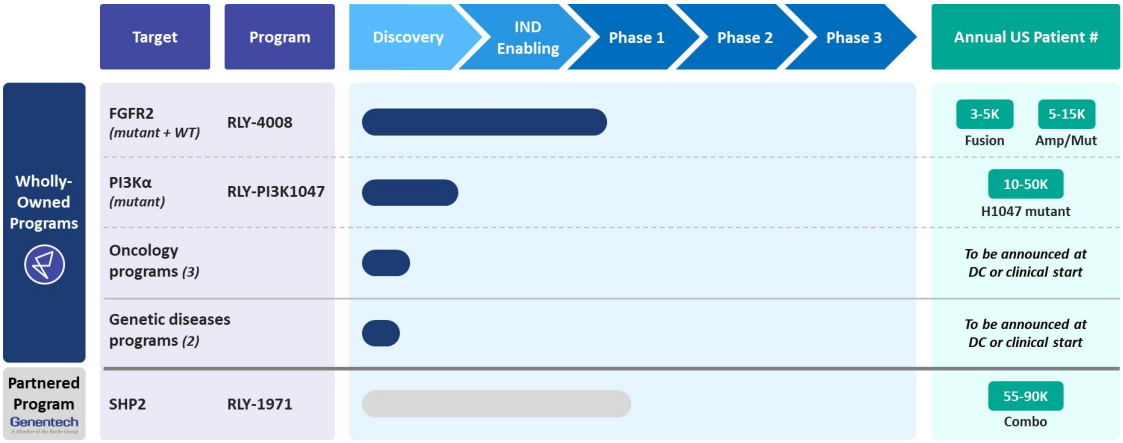
supercomputer, which was custom-built by D. E. Shaw Research, LLC, or D. E. Shaw Research, to perform molecular dynamic simulations of proteins. We have access to the Anton 2 supercomputer, which we believe to be the only resource of computational power of its caliber, through our collaboration with D. E. Shaw Research, LLC, or D.E. Shaw Research, pursuant to which we collaborate with D. E. Shaw Research to rapidly develop various protein models. Our use of the Anton 2 supercomputer and our collaboration with D.E. Shaw Research is subject to the terms and conditions of the Amended and Restated Collaboration and License Agreement with D. E. Shaw Research, or the DESRES Agreement. See "—Our Collaborations—License Agreements and Strategic Collaborations —Collaboration and License Agreement with D. E. Shaw Research, LLC." We deploy the power of the platform in three key phases of MBDD discovery:

- **Target Modulation Hypothesis.** By generating fundamental insights into the structure and conformational dynamics of full-length proteins, our Dynamo platform enables us to model a target protein's function, to develop unique motion-based hypotheses for how to modulate the protein's behavior, and to identify potential novel binding sites for new therapeutic agents.
- **Hit Finding and Lead Generation.** The integration of our computational and experimental platforms affords a deeper functional understanding of our targets and enables the design of physiologically relevant activity-based, ligand-centric and computational screens. These highly differentiated screens have the ability to yield a larger number of chemical series and potential therapies to proceed into lead optimization than conventional experimental techniques alone.
- **Lead Optimization.** Our Dynamo platform uses advanced computational models in tight integration with our medicinal chemistry, structural biology, enzymology and biophysics capabilities to predict, design and experimentally evaluate compounds that will achieve the most desirable characteristics, including potency, selectivity, bioavailability, and drug-like properties. We believe our approach enables us to converge on optimized compounds with much greater efficiency than conventional approaches, which are typically highly iterative over an extended timeframe.

Our Dynamo platform has the potential to address a diverse range of disease targets, including those proteins that have not been addressed selectively and potently with existing therapies. While we have initially focused our Dynamo platform on small molecule drug discovery in the area of precision oncology, we believe it could be readily deployed across broader precision and genetic medicine areas as well as other therapeutic modalities, such as protein therapeutics and antibody design.

Our Programs

We have deployed our technology platform to build a pipeline of product candidates to address targets in precision oncology, where there is clear evidence linking target proteins to disease and where molecular diagnostics can unambiguously identify relevant patients for treatment. We believe this approach will increase the likelihood of successfully translating a specific pharmacological mechanism into clinical benefit. The targets associated with all of our current programs are Category 1 Targets under our DESRES Agreement. See "—Our Collaborations—License Agreements and Strategic Collaborations —Collaboration and License Agreement with D. E. Shaw Research, LLC."



Note: Patient #'s refer to total annual number of US patients with late-line cancers compared to comprehensive annual incidence that may be amenable to treatment with our programs

RLY-4008

RLY-4008 is designed to be an oral, small molecule, selective inhibitor of fibroblast growth factor receptor 2, or FGFR2, a receptor tyrosine kinase that is frequently altered in certain cancers. FGFR2 is one of four members of the FGFR family, a set of closely related proteins with highly similar protein sequences and properties. RLY-4008 demonstrates FGFR2-dependent killing in cancer cell lines, while showing minimal inhibition of other targets, including other members of the FGFR family. We initiated a first-in-human clinical trial of RLY-4008 enriched for patients with advanced solid tumors having oncogenic FGFR2 alterations in September 2020. We anticipate giving an initial clinical update on this trial in the second half of 2021. We believe FGFR2-mediated cancers affect approximately 8,000 late-line patients annually in the United States. In the future, if RLY-4008 advances to earlier lines of treatment, we believe it could potentially address approximately 20,000 patients annually in the United States.

Mutant-PI3Kα Inhibitor Program

RLY-PI3K1047 is a lead compound in our franchise of programs targeting cancer-associated mutant variants of phosphoinositide 3-kinase alpha, or PI3Kα. RLY-PI3K1047 is a small molecule inhibitor of PI3Kα that we designed specifically to target PI3Kα H1047X mutants via a previously undescribed allosteric mechanism. Oral dosing of RLY-PI3K1047 resulted in tumor growth inhibition in mouse xenograft models of PI3Kα H1047R mutant carcinoma. We expect to begin IND-enabling studies for a differentiated PI3Kα H1047X mutant-selective inhibitor in 2021. We believe PI3Kα H1047X mutant cancers affect approximately 10,000 late-line patients annually in the United States. In the future, if RLY-PI3K1047 advances to earlier lines of treatment, we believe it could potentially be suitable for use in approximately 50,000 patients annually in the United States.

Two additional mutations of interest for our PI3Kα franchise are E542X and E545X. We estimate there are approximately 15,000 late-line and 60,000 total patients annually in the United States who might benefit from a PI3Kα targeted inhibitor that targets the mutations at E542 and E545.

RLY-1971

RLY-1971 binds and stabilizes SHP2 in its inactive conformation. SHP2 promotes cancer cell survival and growth through the RAS pathway by transducing signals downstream from receptor tyrosine kinases, or RTKs. Additionally, activating SHP2 mutations causes enhanced signaling in the absence of ligand stimulation and has been identified as an oncogenic driver in a range of tumors. As a critical signaling node and regulator, SHP2 drives cancer cell proliferation and plays a key role in the way cancer cells develop resistance to targeted therapies. We believe that inhibition of SHP2 could be effective as a monotherapy in cancers with specific alterations and could block a common path that cancer cells exploit to resist other antitumor agents, thus overcoming or delaying the onset of resistance to those therapies.

We are currently evaluating the safety and tolerability of RLY-1971 in a Phase 1 dose escalation study in patients with advanced or metastatic solid tumors. In December 2020, we entered into the Genentech Agreement, a global collaboration and license agreement with Genentech for the development and commercialization of RLY-1971. Future development for RLY-1971 will be governed by a joint development team between us and Genentech. We expect a combination trial of RLY-1971 and Genentech's $KRAS^{G12C}$ inhibitor, GDC-6036, to be initiated in 2021. Given the range of cancers that are related to SHP2 dependence, we believe RLY-1971 could serve as a backbone for compelling combination therapies. We believe SHP2-mediated cancers affect approximately 55,000 late-line patients annually in combination therapy settings in the United States. In the future, if RLY-1971 advances to earlier lines of treatment, we believe it could potentially have applicability to approximately 90,000 patients annually in the United States.

Under the terms of the Genentech Agreement, we have received $75 million in an upfront payment and are eligible to receive $25 million in near-term payments; and, if we do not opt into a U.S. profit/cost share, up to $695 million in additional development, commercialization and sales-based milestones for RLY-1971; and tiered royalties on annual global net sales (on a country-by-country basis), in the low-to-mid-teens, subject to reduction in certain circumstances. Additionally, we are eligible to receive additional royalties in the event of regulatory approval of RLY-1971 and Genentech's compound, GDC-6036, that directly binds to and inhibits $KRAS^{G12C}$, in combination. We have the right to opt-in to a 50/50 U.S. profit/cost share and if we do opt into the U.S. profit/cost share, we are eligible to receive up to $410 million in additional commercialization and sales-based milestones for RLY-1971 outside of the U.S. and tiered royalties on annual net sales outside of the U.S. (on a country-by-country basis), in the low-to-mid-teens, subject to reduction in certain circumstances. We also retain the right to develop RLY-1971 in combination with our FGFR2 and PI3Kα programs. If we elect to opt-out of the profit/cost share, then the milestone and royalty payment obligations will revert to the financial terms that would be applicable if we had not opted into the profit/cost share, with certain adjustments. See "—Our Collaborations—License Agreements and Strategic Collaborations—Genentech Collaboration and License Agreement" for more details on the Genentech Agreement.

Discovery Programs

We are deploying our Dynamo platform and MBDD approach to advance multiple discovery-stage precision oncology programs. As with our lead programs, these programs leverage insights into protein conformational dynamics to address high-value, genetically validated oncogenes that previously have been intractable to conventional drug-discovery approaches. Our Dynamo platform's protein visualization capabilities can be applied to multiple therapeutic areas beyond precision oncology. To further diversify our pipeline, we are leveraging our Dynamo platform to address validated targets in monogenic diseases, where genetic alterations lead to disease-causing defects in protein motion.

Our Strategy

Our mission is to leverage unique insights into protein motion to transform the lives of patients suffering from debilitating and life-threatening diseases through the discovery, development and commercialization of small molecule therapies. We believe that, by placing protein motion at the heart of MBDD discovery, our unique Dynamo platform has the potential to address previously intractable precision medicine targets. To accomplish this, we intend to continue building a team that shares our commitment to patients, to continue to enhance our platform,

and to rapidly advance our precision medicine pipeline of product candidates. The key elements of our strategy are to:

Rapidly advance our lead precision oncology programs, RLY-4008 and RLY-PI3K1047, through clinical development and regulatory approval. We believe our lead precision oncology programs have the potential to treat a wide variety of cancers either as monotherapy or in combination regimens. In September 2020, we initiated a first-in-human clinical trial of RLY-4008. In 2021, we expect to have early safety and efficacy data for RLY-4008 and to be in IND-enabling studies for our RLY-PI3K1047 program. For our wholly-owned programs, we plan to conduct our clinical studies in genetically-defined patient populations. To potentially mitigate development risks, we will leverage learnings from recently approved precision oncology drugs to inform the clinical and regulatory pathways for our lead oncology programs. If we are successful in achieving clinically meaningful anti-tumor activity across solid tumor types, we plan to meet with regulatory authorities to discuss expedited regulatory approval strategies.

Continue to enhance our unique drug-discovery platform. Our Dynamo platform uniquely integrates a broad range of leading-edge experimental and computational technologies and tools, providing us with fundamental insights into the conformational dynamics of target proteins. We are committed to continuously integrating new computational and experimental tools, technologies and capabilities to enhance the power of our Dynamo platform.

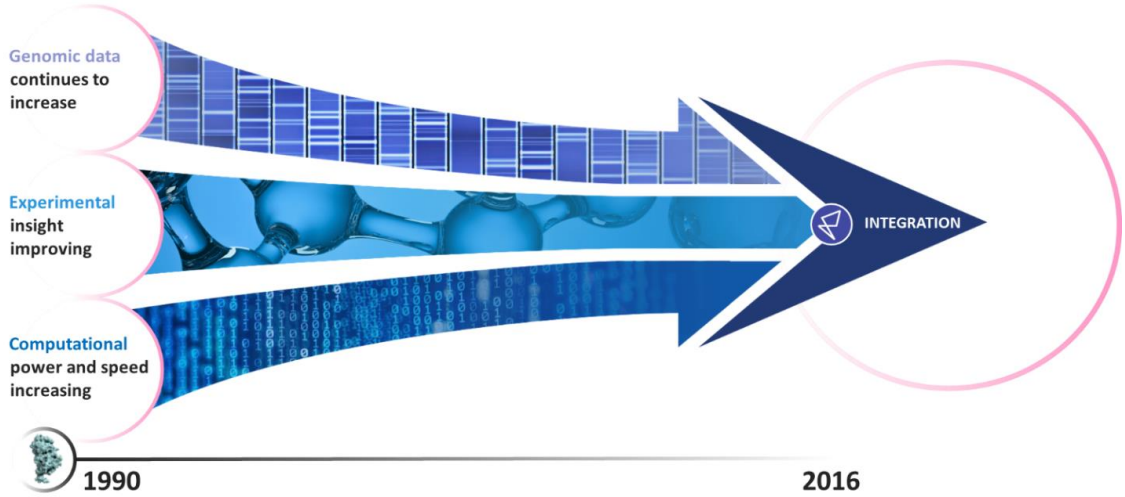
Harness the insights and data generated from our platform against intractable targets in oncology and other therapeutic areas. We have built a drug discovery process that leverages our collaboration with D. E. Shaw Research and their access to the Anton 2 supercomputer and our proprietary computational workflows. We are committed to deploying our Dynamo platform against targets in additional therapeutic areas beyond oncology. Our next focus, outside of oncology, is on rare genetic diseases where protein targets are genetically validated, where defects in protein conformational dynamics are abundant, and where we believe our approach is well-suited to identify therapies with the potential to have transformative impact for patients.

Selectively enter into strategic collaborations to maximize the value of our platform and pipeline. We have initiated a Phase 1 clinical trial for RLY-1971 in patients with advanced solid tumors in the first quarter of 2020 and have continued to advance the clinical development of RLY-1971. In December 2020, we entered into the Genentech Agreement, a global collaboration and license agreement with Genentech for the development and commercialization of RLY-1971. Other than our SHP2 program, we retain full development and commercialization rights to our current pipeline of precision medicine programs. We intend to build a fully integrated biopharmaceutical company and independently pursue the development and commercialization of our key product candidates. Given our potential to generate novel product candidates addressing a wide variety of therapeutic indications, we may enter into additional strategic partnerships around certain targets, product candidates, disease areas or geographies. If we believe these collaborations could accelerate the development and commercialization of our product candidates, and allow us to realize additional potential in our product candidates and our platform.

Our Dynamo Platform

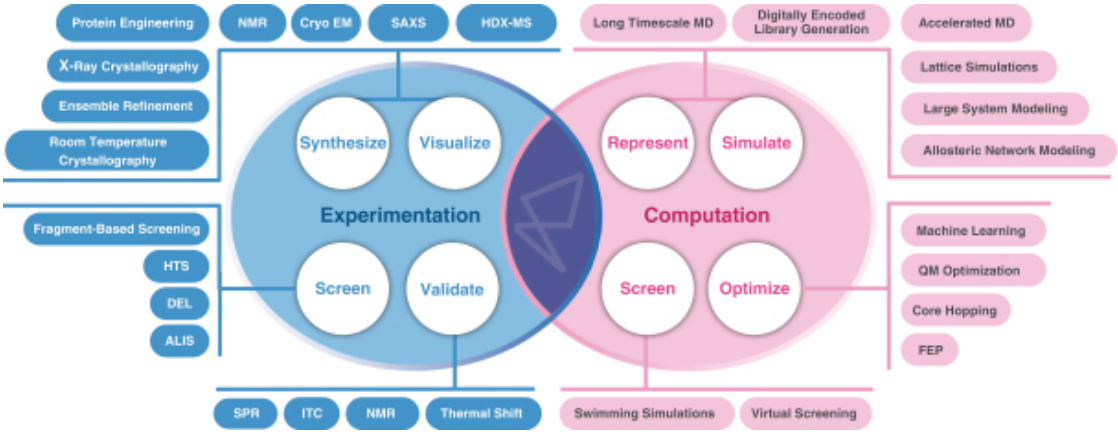
The continued and rapid development of new experimental techniques, such as room-temperature crystallography, and computational techniques, such as molecular dynamics and machine learning, is now enabling the deep understanding of protein motion to discover new therapeutic agents. Dynamo was built to capitalize on these recent advances to develop medicines against protein targets with greater specificity and potency. Using our Dynamo platform, we pivot from industry standard SBDD, which is based on static structures and often relies on incomplete protein fragments, to a novel drug-discovery paradigm based on fundamental insights into protein motion, which we term Motion Based Drug Design, or MBDD. We leverage insights from our platform to develop novel, motion-based hypotheses for how to drug target proteins. We can then more rapidly identify and optimize effective lead compounds by integrating powerful experimental and computational tools to sample a much broader range of chemical space than is possible using conventional approaches, which are labor intensive and require significant experimental effort.

In 2016, the confluence of three forces — the proliferation of readily available genomic data, the evolution of experimental techniques, and advances in computational power and speed — led to the founding of Relay Therapeutics. We believe we are uniquely positioned to consolidate these advances and, when combined with our world-class team of experimental and computational experts, integrate these solutions in motion-based drug discovery.



Our platform integrates a broad and tailored array of leading-edge experimental and computational approaches to gain fundamental insights into protein function (**Figure 1**).

Figure 1: Dynamo drug-discovery platform integrates leading-edge experimental and computational tools.

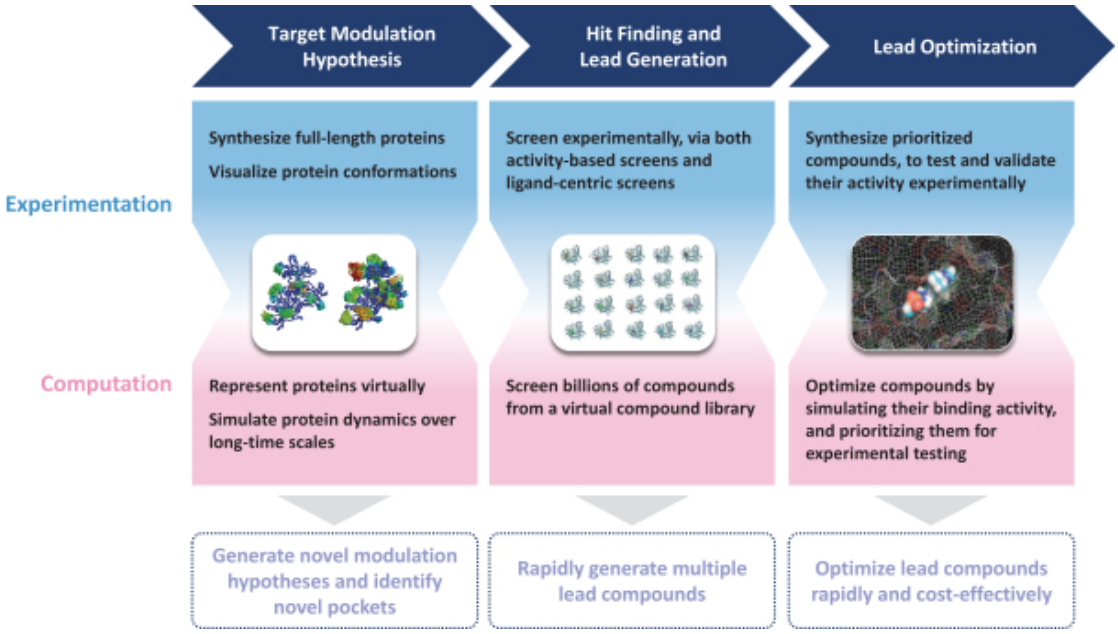


Key Drug Discovery Steps of our Dynamo Platform

We deploy the power of our Dynamo platform in three key phases of MBDD discovery (**Figure 2**). We first generate a target modulation hypothesis by developing a detailed mechanistic understanding of the dynamic behavior of the target protein and by identifying pockets where binding of a small molecule can impact protein function. Our platform then aids in the efficient generation of lead compounds through an integrated system of experimental and virtual screens. This enables rapid lead optimization by computationally prioritizing compounds

for experimental evaluation. As each cycle generates new learnings for both our team and our underlying machine learning models, our successful iteration of this process continuously improves our understanding of protein motion which leads to a more effective and efficient drug discovery process.

Figure 2: Dynamo can be deployed across the various stages of drug discovery to provide novel insights and accelerate drug discovery.



Target Modulation Hypothesis

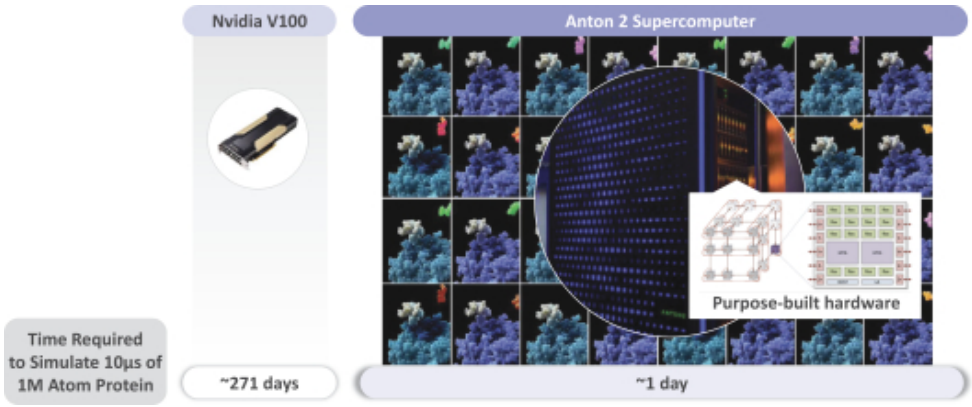
Our first step is to establish a target modulation hypothesis for our protein target of interest.

For each target, the initial goal is to better understand the structure and conformational dynamics of all domains of a protein to generate the target modulation hypothesis. The process typically begins by expressing full-length proteins so we can fully understand the roles of specific domains and accurately capture the differences between the wild-type and mutant forms of the protein (or of different isoforms, etc.). We use a range of leading-edge structural biology techniques (e.g., room temperature X-ray crystallography, Cryo-EM) to visualize these protein conformations in the most physiologically representative context possible. The resulting data allow us to better visualize full-length proteins at atomic resolution. This comprehensive and dynamic visualization enables us to identify potential areas of interest in a protein target that can be exploited in the drug discovery process.

Using a range of protein visualization methods, we can generate a rich experimental understanding of the dynamic conformations of the target protein of interest. We can deploy these experimental data sets in an industry-leading computational platform to generate virtual simulations (molecular dynamics) of the full-length protein moving over long timescales. Long timescale molecular dynamics, or MD, simulations informed by the experimentally derived protein structural data help us better understand how proteins move and change shape over time. Our collaboration with D. E. Shaw Research provides us with access to Anton 2, their proprietary supercomputer that was custom-built for performing molecular dynamics simulations – a technique that calculates the forces between each atom and every other atom in a given system at discrete time points in order to model behavior over time. We use MD simulations to predict the behavior of a given protein system, and with our collaborators we have simulated systems of up to 1 million atoms at time slices of 2.5×10^{-15} seconds. The individual time slices are then stitched together to create a high definition movie of the target protein over biologically relevant timescales, typically tens of

microseconds. Other drug discovery approaches may use molecular dynamics, but they are limited to less than 1/100th of the timescale of our simulations. A 10 microsecond simulation of a 1 million atom benchmark protein (satellite tobacco mosaic virus), which requires one day of processing on the Anton 2, would require 271 days on conventional hardware (Nvidia V100) (**Figure 3**).

Figure 3: The Anton 2 supercomputer enables Relay Therapeutics to simulate the motion of significantly larger biomolecules in far shorter periods of time compared to conventional forms of computation (e.g., GPUs and cloud computing).



After understanding the dynamics of the target protein, we focus on identifying mechanisms to modulate the protein with a small molecule drug. There are multiple ways that a small molecule drug may bind to a target protein to impact its function. Molecules bind to a protein by interacting with amino acids which are often situated in a cavity on the protein's surface, called a pocket. Most small molecule drugs modulate the function of the target protein by binding to the pocket that directly mediates the protein's activity, which is called an "active" site. We leverage our platform to identify novel pockets that are not the active site but do impact protein function, so called "allosteric" sites. These binding sites are often part of an allosteric regulatory network that we can elucidate through a combination of computationally derived hypotheses and laboratory experiments on full-length proteins. Our ability to identify novel druggable pockets that have not previously been observed provides new handles for gaining isoform or mutant selectivity.

Our understanding of protein motion and modulation from our Dynamo platform informs the strategy and tools we employ for hit finding and lead generation phases.

Hit Finding and Lead Generation

Once we have identified potential binding pockets and established a target modulation hypothesis, we then transition into hit finding and lead generation, where the goal is to identify a molecule that can serve as the starting point for a new drug.

Our Dynamo platform leverages our motion-based functional understanding of target proteins to enable the design of physiologically relevant activity-based and ligand-centric screens. These experimental measurements of biochemical or biophysical activity are then used to identify molecules to modulate our protein targets. Our Dynamo platform encompasses a variety of screening techniques to identify chemical starting points.

In parallel to our experimental screening efforts, we have made investments in our infrastructure that enables us to use cloud-computing to screen billions of molecules from a virtual compound library in days. The vast number of virtual molecules enables us to sample a much wider diversity of chemical space than would be possible through conventional methods.

Given the powerful hit finding approaches we utilize, we are able to generate a broad diversity of novel small molecules that act via our motion-based target modulation hypothesis and are ready to progress into lead optimization.

Lead Optimization

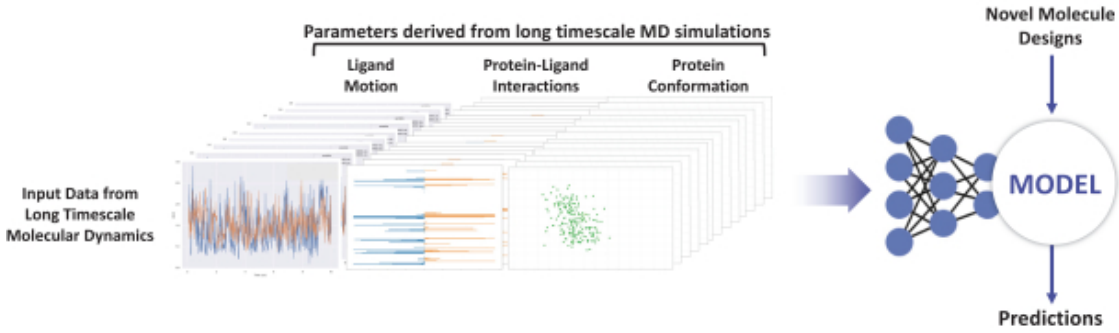
Once we have identified a chemical starting point and generated a lead compound, optimization is necessary to obtain a molecule that has the desired characteristics. Our Dynamo platform uses advanced computational models in tight integration with our medicinal chemistry, structural biology, enzymology and biophysics capabilities to predict and design the compounds that will achieve the most desirable characteristics, including potency, selectivity, bioavailability, and drug-like properties. Conventional optimization of small molecule lead compounds involves a highly iterative process that includes designing and synthesizing thousands of closely related compounds and experimentally testing them in the lab. This process is time consuming and requires significant experimental effort and expense.

During optimization, we leverage long timescale MD simulations to study binding pocket dynamics and to test analogs of our lead compound to prioritize which ones to synthesize and test experimentally.

Once we have made and tested compounds in the lab, we can compare them to our computational predictions. Over time we can improve our computational predictions using the data that we generate experimentally. We believe that this integration of our long timescale molecular dynamics simulations with experimental data accelerates our lead optimization process.

The Anton 2 supercomputer, that we access through our collaboration with D. E. Shaw Research, makes it possible to run thousands of simulations, which generate vast datasets. To take maximum advantage of this data, we use machine learning algorithms to establish relationships between molecular interactions observed in the simulations and biological activity observed in experiments. In **Figure 4**, we show how a machine learning model can be trained based on multiple parameters, including ligand motion, protein-ligand interactions and protein conformation, collected during long timescale MD simulations of molecules interacting with our target protein. This model can then be used to make predictions to prioritize the synthesis of new molecules.

Figure 4: Data from long timescale molecular dynamics simulations are used to train machine learning models that can prioritize the next set of molecules to test.



Benefits of Dynamo Platform

Our Dynamo platform was built with the belief that integrating leading-edge computational and experimental approaches would unlock new insight about protein dynamics and ultimately the drug discovery process. We have shown multiple times that we can use this approach to develop novel target modulation hypotheses, generate a broad range of molecular starting points, and rapidly optimize potential drugs. **Figure 5** illustrates the timelines for our first two programs relative to conventional drug discovery. In general, it takes three to five or more years to advance from a validated hit to a development candidate, or DC. For our programs, however, we were able to advance from

hit to DC in two years for RLY-1971 and 18 months for RLY-4008. In addition to the advantage of speed, as compared to conventional SBDD, our platform enables us to explore a greater diversity of chemical space, as illustrated by the number of chemical series. This breadth increases the intellectual property landscape that we cover and improves our ability to identify development candidates with optimal drug-like properties.

Figure 5: The Relay Therapeutics Dynamo platform compared to conventional drug discovery approaches.

Our Therapeutic Opportunity

While our Dynamo platform could potentially be applied to a wide range of disease-associated protein targets, we currently focus on precision medicine targets, for which alterations in specific genes are known to cause disease. The genetic diseases we pursue include cancers with clear genetic driver alterations in the tumor genome, as well as monogenic diseases where the causal mutations are present at birth.

Precision Oncology

Our initial focus is in the area of precision oncology where we have seen initial proof of platform in our leading precision oncology pipeline. Over 125 genetic driver alterations across 10 canonical cellular signaling pathways have been identified in 89% of tumors. Targeting these genetic drivers could lead to clinically meaningful responses in patients. However, most of these targets have been intractable to conventional drug discovery approaches or are inadequately drugged by approved therapies. We believe our platform has the potential to address many of these targets by leveraging novel insights into protein dynamics.

Monogenic Diseases

Thousands of monogenic (change in a single gene) diseases exist and affect millions of individuals worldwide. Over 4,000 individual genetic drivers, and their associated protein defects, cause over 7,000 rare monogenic phenotypes. However, since 1996, the U.S. Food and Drug Administration, or FDA, has approved fewer than 70 therapies to specifically treat these conditions, presenting a vast unmet therapeutic need. We believe our Dynamo platform has the potential to address many of these targets.

Other Precision Medicines Opportunities

The decreasing cost and increasing resolution of genomic data have identified hundreds of additional actionable genetic targets beyond precision oncology and monogenic disease. These include genetically-defined subpopulations

of more common diseases in neurology, immunology and other therapeutic areas. We believe that there are multiple genetically-validated targets in these disease areas that are unaddressed by approved therapies, representing an area of significant unmet need. We believe our Dynamo platform has the potential to address many of these targets.

Our focus on addressing the genetic drivers of disease, also referred to as genetically validated targets, confers several advantages, including:

Clear causal link to disease: Genetic diseases offer an unambiguous causal link between the mutational alteration in a specific gene, disease biology, and a patient's symptoms, such that the translational medicine hypothesis is well-validated at the beginning of a drug discovery program.

Precision medicine opportunity: Because of the strong link between specific genetic alterations and disease symptoms, it is possible to precisely target therapy to genetically identifiable patients who are most likely to respond favorably to a precision medicine.

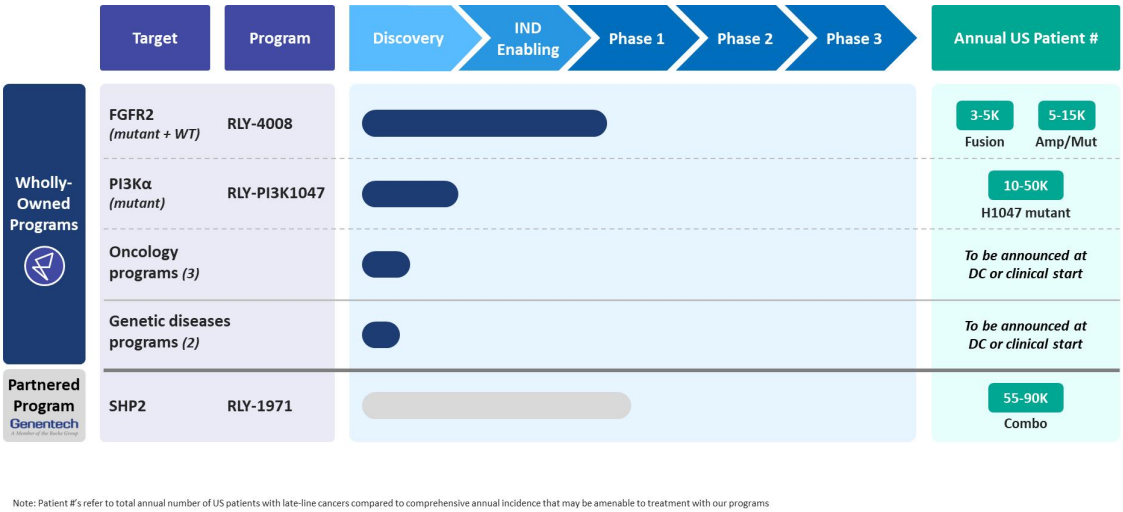
Increased translational success: We believe that the ability to precisely target therapy to patients who are most likely to respond favorably to treatment will, in turn, increase the likelihood of successfully translating a specific pharmacological mechanism into clinical benefit.

While we have initially focused our efforts on small molecule therapies, our Dynamo platform could also be readily deployed towards the discovery of other therapy types, such as large molecules including peptide or protein therapeutics.

Our Product Pipeline and Programs

We have deployed our Dynamo platform to initially focus on the area of precision oncology. To date, we have generated several promising precision oncology, orally available, small molecule product candidates that address previously intractable oncogenic targets. Our lead programs are targeting a range of driver alterations to treat various cancers that we believe can have a greater probability of translational success because they are genetically or clinically validated. The targets associated with all of our current programs are Category 1 Targets under our DESRES Agreement. See "—Our Collaborations—License Agreements and Strategic Collaborations —Collaboration and License Agreement with D. E. Shaw Research, LLC." In addition, we are also advancing several early programs focused on other precision oncology and rare genetic disease targets. In December 2020, we entered into the Genentech Agreement, a global collaboration and license agreement with Genentech for the development and commercialization of RLY-1971. See "—Our Collaborations—License Agreements and Strategic Collaborations—Collaboration and License Agreement with Genentech." Other than our SHP2 program, we retain full development and commercialization rights to our current pipeline of precision medicine programs.

The following table summarizes our current portfolio of product candidates and programs.



Note: Patient #'s refer to total annual number of US patients with late-line cancers compared to comprehensive annual incidence that may be amenable to treatment with our programs

RLY-4008, a selective inhibitor of FGFR2

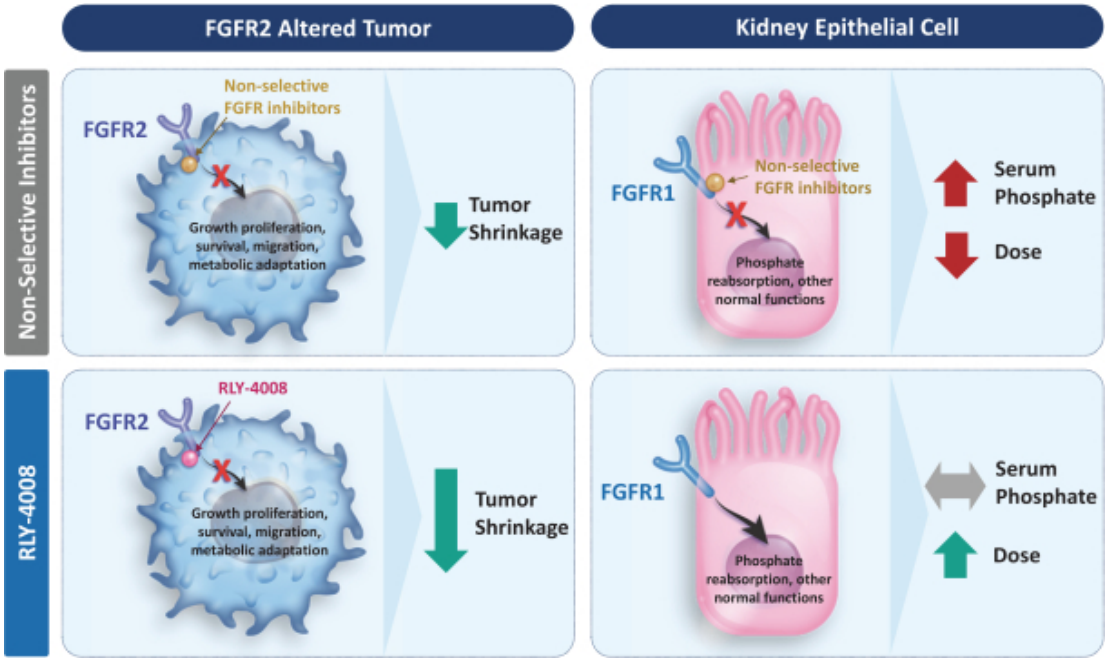
Overview

RLY-4008 is designed to be an oral, small molecule, selective inhibitor of fibroblast growth factor receptor 2, or FGFR2, a receptor tyrosine kinase that is frequently altered in cancer. FGFR2 is one of four members of the FGFR family, a set of closely related proteins with highly similar protein sequences and properties. RLY-4008 minimally inhibits targets other than FGFR2 and demonstrates FGFR2-dependent cell-killing in cancer cell lines. We initiated a first-in-human clinical trial of RLY-4008 enriched for patients with advanced solid tumors having oncogenic FGFR2 alterations in September 2020. We believe FGFR2-mediated cancers affect approximately 8,000 late-line patients annually in the United States, of which fusions represent approximately 2,700, amplifications approximately 1,600, and mutations approximately 3,800. In the future, if RLY-4008 advances to earlier lines of treatment, we believe it could potentially address approximately 20,000 patients annually in the United States across the different alterations.

Role of FGFR in cellular proliferation and differentiation

Each of the FGFRs has an important role in normal physiology and the inhibition of FGFR2 is a well-validated pathway in disrupting cancer proliferation and growth. Two non-selective FGFR inhibitors have been approved (erdafitinib and pemigatinib) and several are in clinical development. However, these inhibitors as a class cause several dose-limiting, FGFR2-unrelated toxicities in patients leading to dose reductions and altered dosing schedules. One of the most common dose limiting toxicities of these agents is hyperphosphatemia (buildup of excess phosphate in the bloodstream), which causes soft tissue mineralization and requires active management. Hyperphosphatemia has been shown to be driven by inhibition of another member of the FGFR family known as FGFR1 (**Figure 15**).

Figure 15: RLY-4008 is a selective inhibitor of FGFR2. FGFR1 is required for phosphate resorption in the kidney. Inhibition of FGFR1 by non-selective FGFR inhibitors results in increased serum phosphate and toxicity. This results in decreased efficacy by requiring dose reductions.



We believe that the toxicity attributable to inhibition of other FGFR family members, and other closely related kinases, limits the ability of the non-selective FGFR inhibitors to achieve optimal and durable inhibition of FGFR2, limiting the efficacy of these agents in patients with FGFR2-altered tumors. In addition to the lack of selectivity, these inhibitors are unable to overcome on-target resistance, which has been observed in patients treated with non-selective FGFR inhibitors. Our belief is that a selective inhibitor of FGFR2 that retains activity against resistance mutations will enable improved clinical efficacy.

Limitations of current FGFR inhibitors

Non-selective FGFR inhibitors produced by other companies have demonstrated clinical proof-of-concept in patients with intrahepatic cholangiocarcinoma, or ICC, bearing FGFR2 gene fusions. These gene fusions result in a constitutively active FGFR2, which promotes oncogenic transformation. Genetic alterations in FGFR2, including gene fusions, amplifications, and point mutations, are also found in other solid tumor indications.

Patients with genetic alterations in FGFR2, primarily gene fusions in ICC, have been treated with FGFR inhibitors in investigational clinical trials. To date, these trials provide support for the critical role of FGFR2 for tumor survival with a response rate of up to 36% (**Figure 16)**. A key limiting factor for existing FGFR therapies is that, as a class, they are associated with a dose-limiting side effect, hyperphosphatemia, which has been shown to be caused by FGFR1 inhibition.

Figure 16: Hyperphosphatemia is a dose-limiting adverse event associated with non-selective FGFR inhibitors.

Compound	Company	Stage	FGFR2 selective	Response Rate	Dosing Schedule	% of Patients with Hyperphosphatemia	% of Patients Discontinued or Dose Reduced
Pemigatinib	Incyte	Approved	No	36% (iCC)	2 weeks on, 1 week off	94%	23%
Infigratinib	QED	Phase 2/3	No	27% (iCC)	3 weeks on, 1 week off	62%	61%
TAS-120	Taiho	Phase 2/3	No	37% (iCC)	Once daily dosing	88%	52%
Erdafitinib	Janssen	Approved	No	32% (Urothelial Carcinoma)	Personalized dosing*	76%	66%

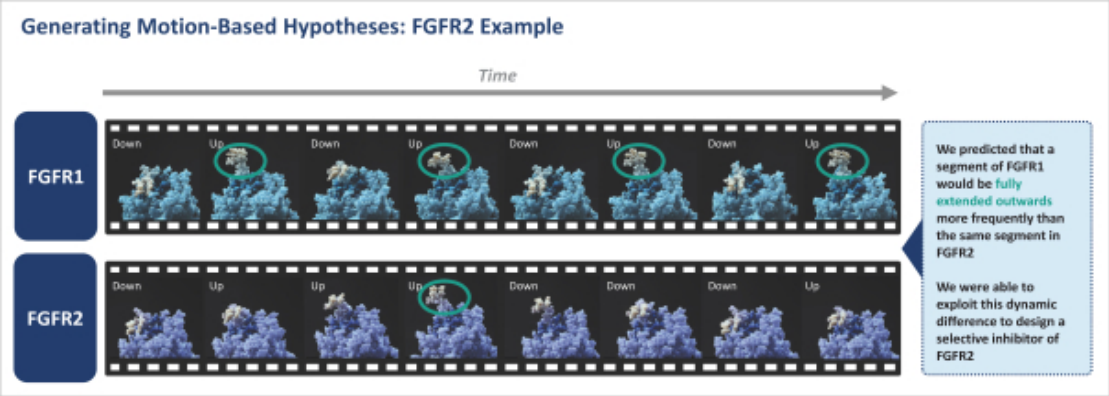
*Initial dose (8mg QD) adjusted to 9mg QD only in absence of hyperphosphatemia
Data references: Pemigatinib – ESMO 2019; Infigratinib – BridgeBio S-1; TAS-120 – ASCO 2020 Presentation of Interim Analysis; Erdafitinib – Prescribing information; N.R. = not reported

Our solution, RLY-4008

RLY-4008 is an oral, small molecule inhibitor of FGFR2 designed to inhibit FGFR2 with high potency while minimizing inhibition of other FGFR family members. In our initial assessment of the challenge of obtaining a highly selective inhibitor of FGFR2, we determined that there is a high degree of structural similarity between FGFR1 and FGFR2 when comparing static X-ray crystal structures. This similarity precluded the development of a structure-based selectivity hypothesis using conventional approaches.

We therefore set out to identify motion-based differences between FGFR2 and other FGFR family members by applying our expertise in computational modeling and experimental structural analyses. We discovered that there were segments of FGFR2 which displayed differential dynamics compared to the corresponding segments of FGFR1 (**Figure 17**). We predicted these dynamic differences could be exploited to achieve selective inhibition of FGFR2.

Figure 17: Using MD simulations, we predicted that a segment in FGFR1 was more dynamic than FGFR2, as represented by the schematic below where the segment opens "Up" more frequently in FGFR1 compared to FGFR2.



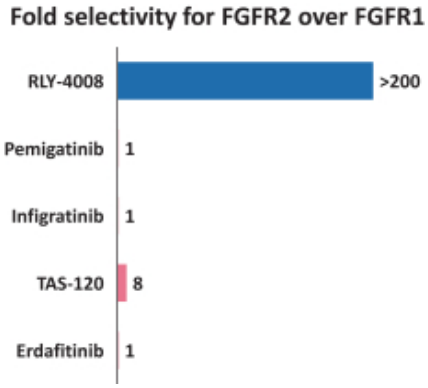
We embarked on a process using computational methods such as long timescale molecular dynamics simulations, virtual docking and specialized experimental techniques to design, select, synthesize, and evaluate inhibitors. Our discovery process culminated with the selection of RLY-4008 as a product candidate based on its ability to meet our predetermined criteria for potency, selectivity and activity in animal models.

As described below, we have conducted a number of head-to-head preclinical experiments utilizing cellular *in vitro* assays and mouse models using equivalent methods on all compounds tested. We compared RLY-4008 across a number of parameters against two approved molecules as well as three molecules in clinical development. We believe that the results of these preclinical experiments have demonstrated that RLY-4008 could potentially be a differentiated molecule warranting testing in clinical studies. We initiated a first-in-human clinical trial of RLY-4008 enriched for patients with advanced solid tumors having oncogenic FGFR2 alterations in September 2020. Given RLY-4008's strong preclinical activity against both primary oncogenic alterations and acquired pan-FGFR inhibitor resistance mutations, the trial will include patients that are naïve to pan-FGFR inhibitors, as well as those that have progressed on pan-FGFR inhibitors. Ultimately, extensive clinical studies of RLY-4008 will be required to determine if the differentiation we observed in the preclinical studies described below translates into clinical benefit for patients. The clinical data that we expect to generate in any such clinical studies will constitute the bulk of the data needed to support an application for marketing approval of RLY-4008. Unless we conduct head-to-head studies of RLY-4008 against other molecules as part of our future clinical trials, we would not expect to rely upon RLY-4008's potential differentiation from any other molecules in connection with submissions to the FDA or other regulatory agencies, as applicable, for approval or otherwise.

In addition, in our head-to head preclinical experiments utilizing cellular *in vitro* assays and mouse models, we selected dose levels for the other molecules to match human exposure of the approved dose or the dose being used in its clinical studies, as applicable, and we used the proportional dose levels of RLY-4008 that we believe are comparable to what we expect to utilize in our future clinical studies. The differences in these dose levels may have had an impact on the differentiation in the preclinical results we observed.

We demonstrated in enzymatic and cellular assays that RLY-4008 was over 200-fold more potent at inhibiting FGFR2 compared to FGFR1 (**Figure 18**). In addition to selectivity over FGFR1, RLY-4008 is also selective over the other members of the FGFR family, FGFR3 (>80-fold) and FGFR4 (>4,000 fold) in biochemical assays.

Figure 18: RLY-4008 is selective for FGFR2 over FGFR1.



The selectivity of RLY-4008 for FGFR2 over FGFR1 was determined by comparing the potency (IC50) of RLY-4008 and other clinical non-selective FGFR inhibitors in biochemical assays using Caliper technology (PerkinElmer). Human FGFR1 and FGFR2 (Carna Biosciences) were incubated with a peptide substrate (PerkinElmer) in the presence of varying concentrations of the indicated inhibitor for 30 minutes. Reactions were carried out in the presence of 100 mM ATP and 10 mM MgCl2 for 90 minutes. Non-selective FGFR inhibitors were obtained from vendors that provide compounds based on chemical structures published in the patent literature (Cayman Chemical, MedChemExpress, Selleckchem). Fold change in potency was calculated using the average IC50 obtained for each inhibitor in three independent experiments. RLY-4008 showed greater than 200-fold selectivity for FGFR2 over FGFR1.

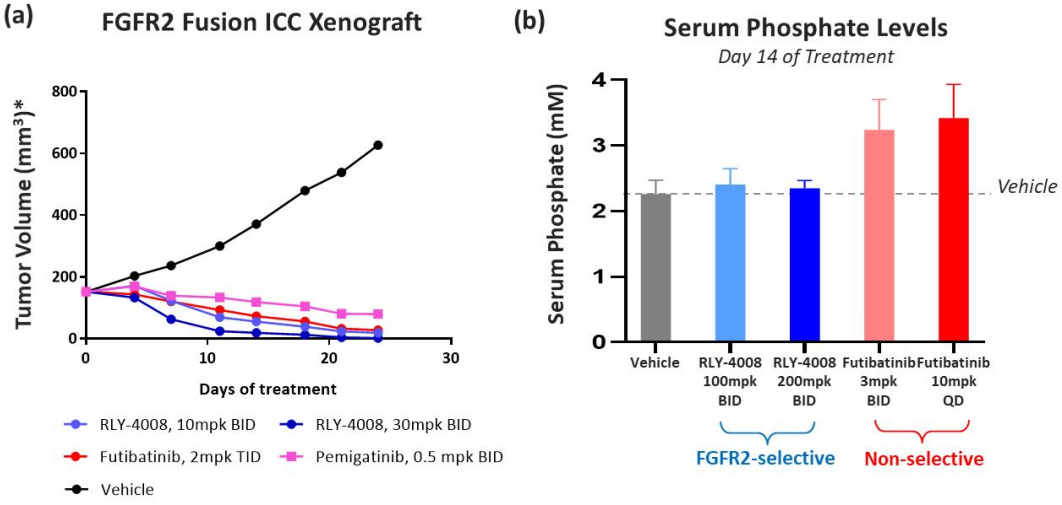
RLY-4008 has minimal inhibition of targets other than FGFR2 and demonstrates FGFR2-dependent cell-killing in cancer cell lines. It has bioavailability suitable for oral dosing, is metabolically stable, and has demonstrated good

pharmacokinetics in preclinical *in vivo* models. Human pharmacokinetic projections are consistent with once or twice daily oral dosing. RLY-4008 is predicted to have low risk of drug-drug interactions based on weak inhibition of drug metabolizing enzymes. It is readily synthesized in bulk, can be formulated for oral delivery, and exposures at the highest non-severely toxic dose were several fold in excess of the predicted human efficacious exposures.

In a patient-derived xenograft, or PDX, mouse model of ICC harboring a FGFR2 fusion, treatment with RLY-4008 led to tumor regression at doses as low as 10 mg/kg delivered twice a day (**Figure 19**). Non-selective inhibitors, pemigatinib and futibatinib, also resulted in tumor volume reductions in this model when dosed at levels selected to match their human exposure in clinical studies.

To preclinically validate our effort to engineer selectivity for FGFR2 as a means of reducing the risk of hyperphosphatemia, we examined the effect of RLY-4008 in an industry standard rat model of hyperphosphatemia. No evidence of hyperphosphatemia was seen with doses of RLY-4008 that resulted in exposures leading to tumor regression in our FGFR2 gene fusion ICC PDX mouse model (**Figure 19**). By contrast, when dosed at levels selected to match human exposure in clinical studies, futibatinib led to increased hyperphosphatemia. Additionally, in 28-day GLP toxicology studies in rats and dogs, neither hyperphosphatemia nor tissue mineralization were observed with RLY-4008 at exposures in the animal corresponding to the predicted human efficacious exposures.

Figure 19: RLY-4008 leads to tumor regression in an FGFR2 fusion positive ICC PDX model and does not cause hyperphosphatemia.

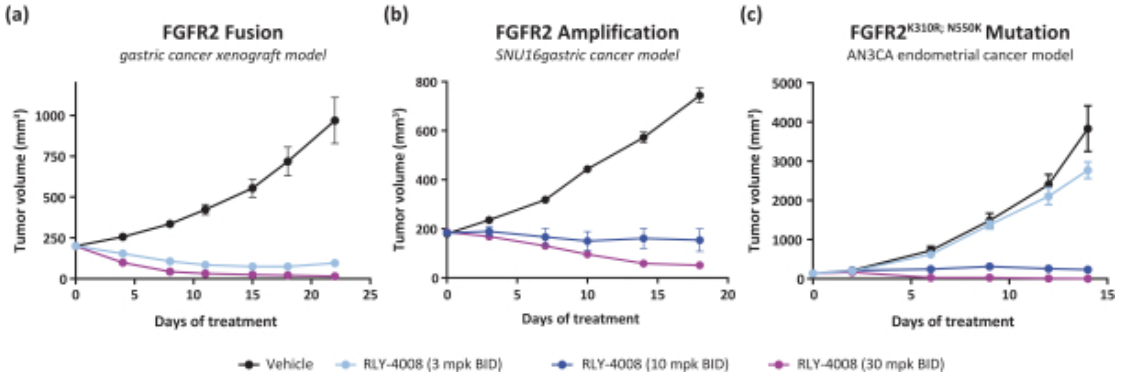


(a) *Anti-tumor activity of RLY-4008 dosed twice daily (BID) by oral administration in an FGFR2 fusion-positive ICC PDX model. RLY-4008 induced dose-dependent regression when administered at 10 or 30 mpk BID. TAS-120 at 2 mpk TID (red) and pemigatinib at 0.5 mpk BID (pink) were dosed at levels selected to match their clinical exposures. Data points indicate mean tumor volume (n=6 per group) and error bars represent standard error of the mean. All treatment groups are statistically significant when compared to vehicle with p<0.001 as determined by two-sided t-test.*

(b) *Serum phosphate measurements in rats dosed twice daily with RLY-4008 (blue) or TAS-120 (red) by oral administration. Doses of RLY-4008 (100 and 200 mpk BID) resulting in exposures leading to tumor regression in our FGFR2 gene fusion ICC PDX model do not cause significant hyperphosphatemia. Doses of TAS-120 (3 mpk BID and 10 mpk QD) selected to match human exposures in clinical studies cause significant hyperphosphatemia. Data indicate the mean serum phosphate level (n=5 per group), and error bars represent standard deviation. TAS-120 treatment groups are statistically significant when compared to vehicle with p<0.01 as determined by one-way ANOVA.*

Additionally, RLY-4008 was able to achieve *in vivo* efficacy in mouse models of FGFR2-fusion gastric cancer, FGFR2-amplified gastric cancer, and FGFR2-mutant endometrial cancer. Treatment with RLY-4008 led to tumor regression at 3 mg/kg delivered twice a day in a FGFR2 gene fusion gastric cancer model, and at 10 mg/kg delivered twice a day in a FGFR2-amplified gastric cancer or FGFR2-mutant endometrial cancer models (**Figure 22**). All of these doses result in exposures that do not cause hyperphosphatemia in an industry standard rat model. Importantly, RLY-4008 achieved complete regression in an FGFR2-mutant endometrial cancer model (AN3CA) harboring the N550K mutation that reduced the potency of pemigatinib by 185-fold.

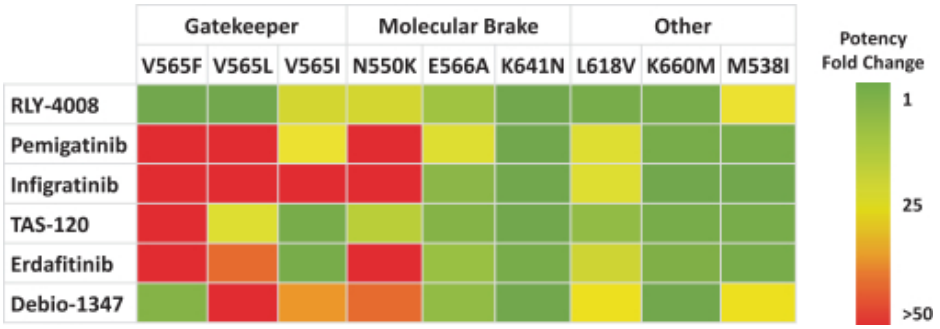
Figure 22: RLY-4008 leads to tumor regression in an FGFR2-fusion gastric cancer PDX, the FGFR2-amplified gastric cancer SNU16 xenograft model, and the FGFR2 N550K-mutant endometrial cancer AN3CA xenograft model.



Anti-tumor activity of RLY-4008 dosed twice daily (BID) by oral administration in **(a)** *an FGFR2 fusion gastric cancer PDX model,* **(b)** *the FGFR2-amplified SNU16 gastric cancer xenograft model, and* **(c)** *the FGFR2 K310R; N550K mutant AN3CA endometrial cancer xenograft model. Data points indicate mean tumor volume and error bars represent standard error of the mean. Statistical analyses were performed using one-way ANOVA. (a) n=8 per group; treatment groups are statistically significant when compared to vehicle with p<0.001. (b) n=7 per group; treatment groups are statistically significant when compared to vehicle with p=0.001 for 10 mpk BID group and p<0.001 for 30 mpk BID group. (c) n=8 per group; two high-dose groups are statistically significant when compared to vehicle with p=0.003 for 30 mpk BID group and p=0.005 for 10 mpk BID group. p=0.627 for 3 mpk BID group.*

Another predicted advantage of RLY-4008 concerns resistance mutations. These new mutations in FGFR2 arise during treatment, reducing the potency of non-selective FGFR inhibitors and making tumors resistant to treatment. In preclinical experiments, we have shown that RLY-4008 retains activity against a broad panel of mutations known to be associated with resistance to non-selective FGFR inhibitors (**Figure 20)**.

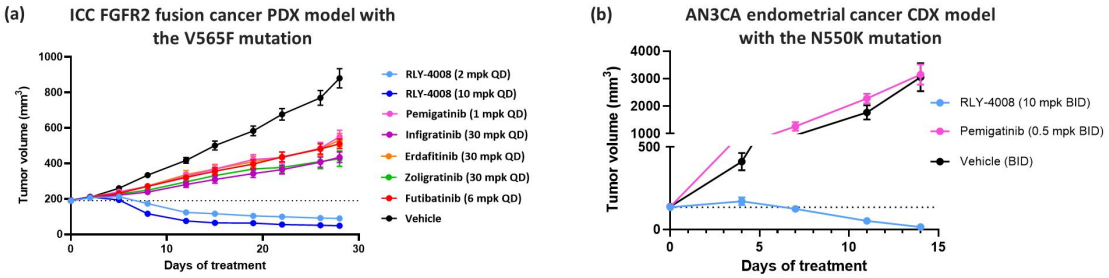
Figure 20: RLY-4008 retains potency against common FGFR2 resistance mutations.



Heatmap showing fold change in potency (IC50) on FGFR2 mutations compared to FGFR2 WT. Human FGFR2 cDNA (NCBI Reference Sequence: NM_022970.3) was cloned into pLenti-P2A-Puro vector, site-directed mutagenesis was performed for the indicated mutations, and plasmid purification was conducted at GenScript. Lentivirus for each vector was prepared using Lenti-vpak Lentiviral Packaging Kit, and FGFR2 WT or FGFR2 mutants were expressed in HEK-293 cells via lentiviral transduction. Cells were incubated with various concentrations of the indicated inhibitors for 2 hours and potency of FGFR2 was determined using a pFGFR2 (Tyr 653/654) HTRF assay (Cisbio) per the manufacturer's protocol. Colors indicate the fold loss in potency for the mutant FGFR2 vs WT. Gatekeeper mutations block access to the binding site of non-selective inhibitors. Molecular brake mutations disrupt an autoinhibitory conformation of FGFR2, resulting in kinase activation. Other mutations listed have various reported mechanisms of kinase activation.

In the studies published to date describing resistance, multiple FGFR2 resistance mutations have been reported, with mutations at position V565 and N550 being most common. Mutations sterically block access to the binding site of non-selective FGFR inhibitors and/or disrupt an auto-inhibitory conformation of FGFR2. Among mutations, V565F and N550K are two of the most prevalent. To further evaluate the activity of RLY-4008 against FGFR2 resistance mutations, the *in vivo* activity of RLY-4008 was compared to five different pan-FGFR inhibitors including pemigatinib, infigratinib, erdafitinib, zoligratinib, and futibatinib in an ICC FGFR2 fusion cancer PDX model with the V565F mutation and to pemigatinib in the AN3CA endometrial cancer CDX model with the N550K mutation. In both models, RLY-4008 was able to induce regression at doses resulting in exposures that do not cause hyperphosphatemia in an industry standard rat model. By contrast, when dosed at levels selected to approximate human exposure in clinical studies, the pan-FGFR inhibitors showed little to no anti-tumor activity in both models (**Figure 23**).

Figure 23: RLY-4008 induces tumor regression in FGFR2 V565F and N550K-mutant xenograft models.

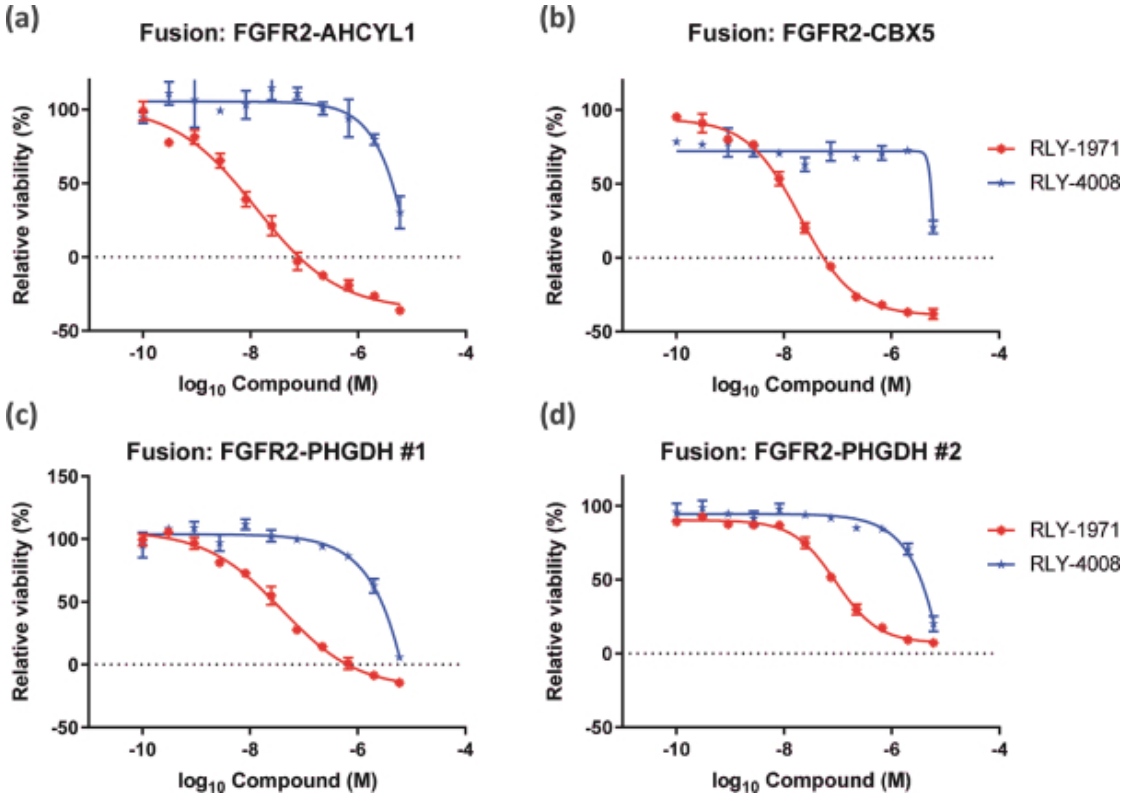


Anti-tumor activity of RLY-4008 and pan-FGFR inhibitors in xenograft models harboring common on-target resistance mutations. (a) RLY-4008 and pan-FGFR inhibitors were dosed once daily (QD) by oral administration in an ICC FGFR2 fusion cancer PDX model with the V565F mutation. RLY-4008 induced regression whereas all pan

FGFR inhibitors grew in the presence of drug. (b) RLY-4008 and pemigatinib dosed twice daily (BID) by oral administration in the FGFR2 K310R;N550K mutant AN3CA endometrial cancer xenograft model. RLY-4008 induced regression whereas pemigatinib was inactive. Data points indicate mean tumor volume and error bars represent standard error of the mean. RLY-4008 cohort is statistically significant when compared to vehicle or pan-FGFR inhibitors with p<0.001 as determined by one-way ANOVA.

Although RLY-4008 retains activity preclinically against common FGFR2 resistance mutations, tumors may develop bypass resistance by shifting growth factor signaling to an alternate receptor, rendering them less sensitive to the targeted therapy. SHP2, a protein tyrosine phosphatase, regulates the activity of multiple RTKs, and may be an effective way to overcome bypass resistance to RLY-4008. To demonstrate the potential for RLY-1971 as a combination partner for RLY-4008, we tested a population of four patient-derived FGFR2-fusion positive ICC cell lines. These cells were derived from patients that initially responded to non-selective FGFR inhibitors, but then acquired bypass resistance to FGFR inhibition during their treatment. While these cell lines were resistant to treatment with our FGFR2 inhibitor RLY-4008, all resistant cells were sensitive to RLY-1971 with IC50s of less than 100 nM (**Figure 24**). Given the role of SHP2 in mediating bypass resistance to multiple targeted therapies, we intend to investigate the clinical potential of the combination of RLY-1971 with RLY-4008.

Figure 24: RLY-1971 overcomes bypass resistance to FGFR2 inhibition in patient-derived FGFR2 fusion positive ICC cell lines.



Anti-proliferative effect of RLY-1971 in patient-derived FGFR2 fusion positive ICC cells tested in a 2D proliferation assay. These cell models were derived from patients that initially responded to non-selective FGFR inhibitors, but then progressed during their treatment (the specific FGFR2 fusion present in the cells is indicated). These cells are resistant to treatment with our FGFR2 inhibitor RLY-4008 (blue lines), whereas RLY-1971 demonstrates anti-

proliferative and cytotoxic activity (red lines), with IC50s as follows: ***(a)*** *13 nM,* ***(b)*** *20 nM,* ***(c)*** *39 nM, and* ***(d)*** *91 nM. The dotted line at 0 indicates complete growth suppression, with values below 0 indicating cytotoxicity.*

Our clinical development plan

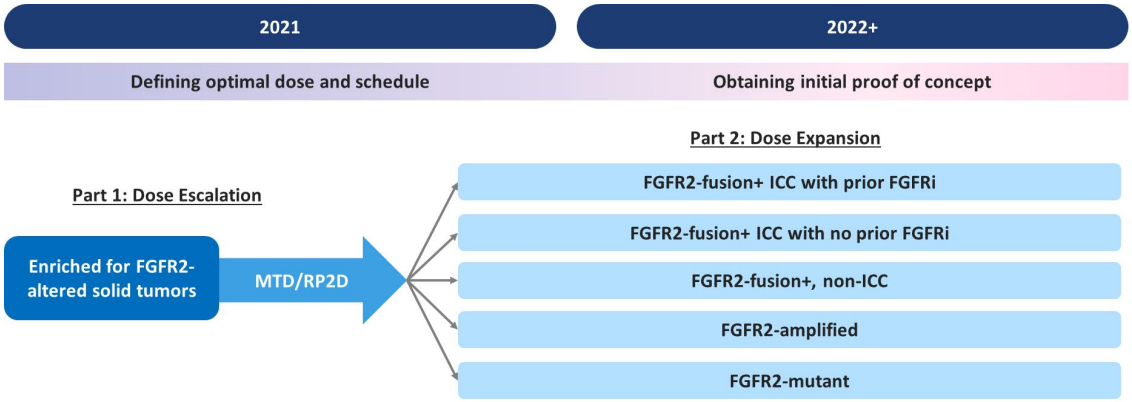
The RLY-4008 clinical development plan seeks to leverage the unique potential for enhanced tolerability and broad FGFR2 mutational coverage to rapidly generate proof-of-concept in molecularly defined patient subsets.

We initiated a first-in-human clinical trial of RLY-4008 enriched for patients with advanced solid tumors having oncogenic FGFR2 alterations in September 2020. The primary objectives are to determine the maximum tolerated dose (MTD)/recommended phase 2 dose (RP2D) and to define the overall safety profile of RLY-4008. Secondary objectives are to assess the pharmacokinetics, pharmacodynamics and to explore anti-tumor activity of RLY-4008. Patients will initially receive RLY-4008 administered orally, twice daily.

The first trial will employ a 2-part dose escalation/dose-expansion design. Given RLY-4008's strong preclinical activity against both primary oncogenic alterations and acquired pan-FGFR inhibitor resistance mutations, the trial will include patients that are naïve to pan-FGFR inhibitors, as well as those that have progressed on pan-FGFR inhibitors. Observation of significant clinical activity in one or more patient populations in this exploratory first-in-human trial would support further trials to confirm the risk-benefit profile of RLY-4008 in patients with oncogenic FGFR2 alterations. These trials may include continued evaluation of RLY-4008 as a monotherapy in single arm trials in patient populations without an established standard-of-care therapy available, which could be used to support filings for marketing authorization for RLY-4008. The development program for RLY-4008 may also include randomized trials of RLY-4008 compared to a relevant standard-of-care therapy.

We anticipate giving an initial clinical update on this trial in the second half of 2021.

Figure 25: First-in-human clinical trial for RLY-4008



Development of RLY-4008 will require identification of appropriate patients for treatment with FGFR2 alterations using molecular diagnostic tests. In early phase clinical trials, patients will be identified using local testing performed at clinical trial sites, with retrospective centralized testing to confirm the tumor genetic status. In later phase trials, we will likely collaborate with a diagnostic partner to identify patients for clinical trial enrollment using an analytically validated investigational molecular diagnostic. The tumor genetic contexts that we are considering for development of RLY-4008 (FGFR2 fusions, amplifications and mutations) can currently be detected using FDA-approved next generation sequencing based panel diagnostics (e.g. Foundation One, Guardant 360).

Mutant-PI3Kα Inhibitor Programs

Overview

RLY-PI3K1047 is the lead compound in our franchise of programs targeting cancer-associated mutant variants of phosphoinositide 3-kinase alpha, or PI3Kα. RLY-PI3K1047 is a small molecule inhibitor of PI3Kα that we designed to specifically target PI3Kα H1047X mutant via a previously undescribed allosteric mechanism. Oral dosing of RLY-PI3K1047 resulted in tumor growth inhibition in a mouse xenograft model of PI3Kα H1047R mutant carcinoma. We expect to begin IND-enabling studies for a differentiated PI3Kα H1047X mutant-selective inhibitor in 2021. We believe PI3Kα H1047X mutant cancers affect approximately 10,000 late-line patients annually in the United States. In the future, if RLY-PI3K1047 advances to earlier lines of treatment, it could potentially address approximately 50,000 patients annually in the United States.

Two additional mutations of interest for our PI3Kα franchise are E542X and E545X. We estimate there are approximately 15,000 late-line and 60,000 total patients annually in the United States who might benefit from a PI3Kα targeted inhibitor that targets the mutations at E542 and E545.

Figure 26: PI3Kα addressable patient populations

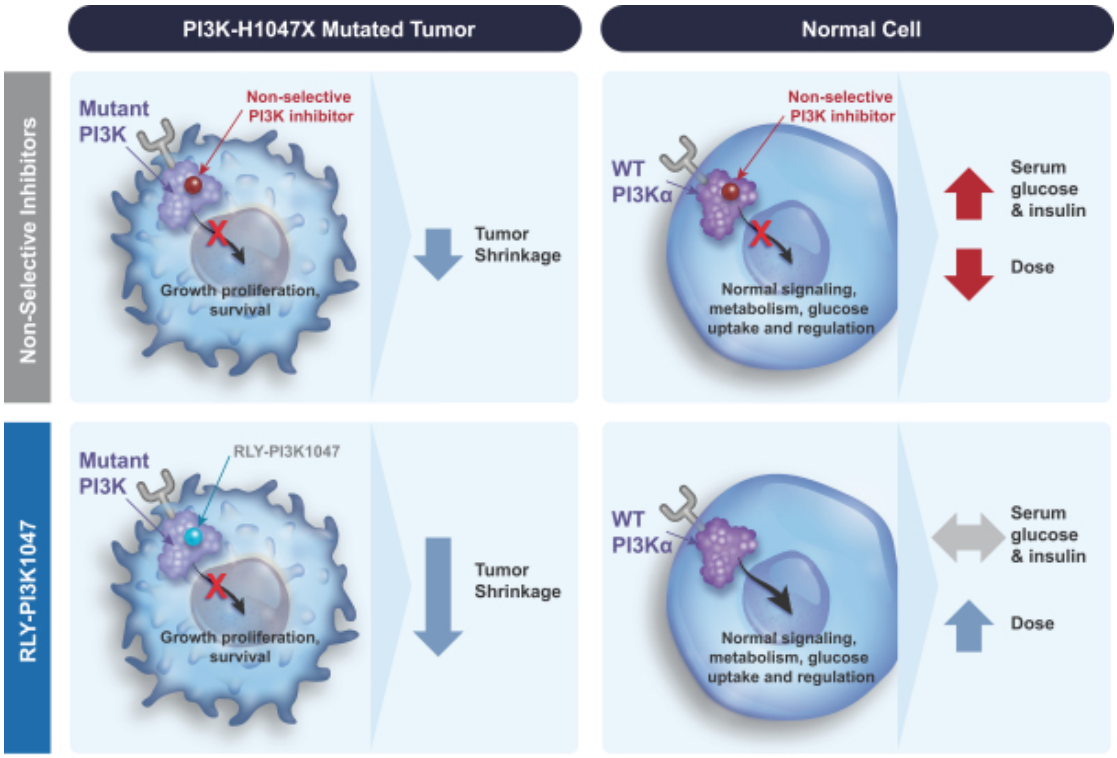
PI3Kα					
H1047X Mutations					
Indication Biomarker Frequency [1]	Breast Cancer 13.9%	Colorectal Cancer 3.0%	Endometrial Cancer 8.2%	Lung Cancer 0.9%	Total
Biomarker Positive Late Line Incidence [2]	6,000	2,000	1,000	1,000	10,000
Biomarker Positive Comprehensive Incidence [3]	37,000	4,000	5,000	2,000	48,000
E542X/E545X Mutations					
Indication Biomarker Frequency [1]	Breast Cancer 11.6%	Colorectal Cancer 8.3%	Endometrial Cancer 9.4%	Lung Cancer 3.6%	Total
Biomarker Positive Late Line Incidence [2]	5,000	4,000	1,000	5,000	15,000
Biomarker Positive Comprehensive Incidence [3]	31,000	12,000	6,000	8,000	57,000

1) Estimated frequency percentages are based on counts of known/likely functional alterations in the Foundation Medicine Insights database. 2) Based on projected cancer deaths in all solid tumors from the National Cancer Society's SEER database as a proxy for late-line cancer patient incidence. 3) These data are based on projections from the National Cancer Society's SEER program for estimated new cases of advanced solid tumors.

Role of PI3Kα in cellular proliferation and differentiation

Mutations at amino acid H1047 of PI3Kα are among the most common kinase mutations in cancer and are believed to be a primary driver of carcinogenesis. There are no approved therapies that selectively target mutant versions of PI3Kα. Inhibitors that are not mutant-selective are associated with dose-limiting toxicities resulting in frequent discontinuations that restrict their therapeutic potential. Additionally, these inhibitors also can inhibit other isoforms of PI3K, including PI3Kδ, which can further result in toxicity. Our belief is that selectively targeting mutant PI3Kα could result in improved target inhibition and increased clinical efficacy (**Figure 27**).

Figure 27: RLY-PI3K1047 is a selective inhibitor of H1047X mutant PI3Kα. WT PI3Kα plays a critical role in normal cellular signaling and function, including glucose uptake and insulin regulation. Inhibition of WT PI3Kα by non-mutant selective PI3K inhibitors results in hyperglycemia, hyperinsulinemia and other toxicities. This results in decreased efficacy by requiring dose reductions.

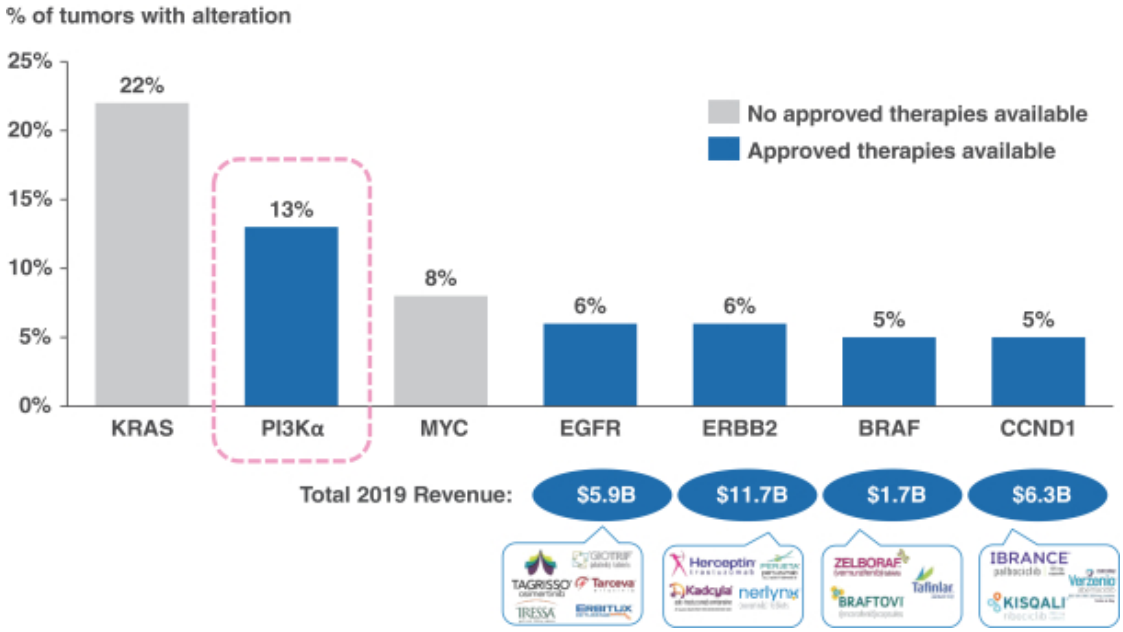


Leveraging our structural biology capabilities, we solved what we believe to be the first full-length structure of PI3Kα using cyrogenic electron microscopy (Cryo-EM) and utilized a range of experimental techniques to understand both H1047R mutant and wild-type conformations. We used this rich experimental data set to power molecular dynamics simulations of H1047R mutant PI3Kα to identify a series of dynamic structural changes caused by the mutation, which were not elucidated by prior structural studies of either H1047R mutant or wild-type PI3Kα. The lead compound in this program, which we refer to as RLY-PI3K1047, was designed to exploit these dynamic differences and bind to a novel allosteric site to achieve heightened mutant selectivity. We intend to initiate IND-enabling studies for our first PI3Kα mutant selective inhibitor, which is focused on H1047X, in 2021.

PI3Kα mutations drive the development of cancer

PI3Kα is the central regulator of a cellular signaling pathway that has been linked to a diverse group of cellular functions related to cancer including cell growth, proliferation and survival. Data collected as a part of Foundation Medicine Insights and other data sources identifies PI3Kα as the most frequently mutated kinase in cancer. (**Figure 28**).

Figure 28: PI3Kα is a common mutation in cancer.



Approximately 80% of the mutations in PI3Kα cluster at three amino acids, or locations. These are E542 and E545 in the helical domain, and H1047 in the kinase domain. The most common mutation at amino acid H1047 is H1047R, but other H1047 mutations (such as H1047L, H1047Y, and others) are also observed across cancers. The abbreviation "H1047X" is used to refer to any H1047 mutation. Similarly, the most common mutations in the helical domain are E542K and E545K, but other mutations (such as E542Q, E545A, and others) are also observed across cancers. The abbreviation "E542/E545X" is used to refer to any helical domain mutation. The H1047R mutation has been shown to induce extensive and diverse cellular changes in pre-clinical models of breast cancer, demonstrating how a single mutation at amino acid H1047 can have large consequences and induce a cancer phenotype. The E5452K and E545K mutations have also been shown to increase PI3Kα activity, promote cell growth and invasion in vitro, and induce tumorigenesis in vivo. While H1047X and E542/E545X mutations have been shown to result in aberrant PI3Kα activity, they do so through distinct biological mechanisms.

Limitations of current PI3Kα inhibitors

Given the large number of patients with PI3Kα mutations, several small-molecule inhibitors of PI3Kα are in development for oncology indications. However, these inhibitors have to our knowledge been largely ineffective when used as monotherapy in cancer. All of these inhibitors target the catalytic (orthosteric) site of PI3Kα. One challenge faced by these inhibitors has been drug intolerance, especially at the high doses routinely used in cancer trials. Alpelisib, marketed as Piqray® by Novartis, is the only FDA-approved inhibitor for cancers with mutated PI3Kα. However, alpelisib is not a selective inhibitor for mutant forms of PI3Kα; it is a potent inhibitor of both the wild-type form of PI3Kα as well as the mutant form. Nonetheless, alpelisib is approved to be used in combination with fulvestrant, an estrogen receptor degrader, in PI3Kα-mutated breast cancer. When used in combination with fulvestrant, alpelisib was associated with significant adverse events, including severe hypersensitivity, diarrhea and severe pneumonitis. Hyperglycemia was reported in 64% of patients and over 36% of patients experienced Grade 3 or Grade 4 hyperglycemia. To manage hyperglycemia, insulin along with other anti-diabetic medication was used in 87% of patients. Gastrointestinal toxicity was reported in 93% of patients, with 9% experiencing Grade 3 gastrointestinal toxicity. Additionally, 36% of patients experienced rash, with 10% experiencing Grade 3 rash. The combination of these adverse events resulted in 64% of patients requiring dose reductions and 25% of patients discontinuing treatment. Despite 11 month progression-free survival (PFS) in the SOLAR-1 Phase 3 trial of alpelisib, the median duration of dosing in the alpelisib arm was 5.5 months, indicating the majority of patients

discontinued dosing prior to disease progression. The observed hyperglycemia is believed to be caused by inhibition of wild-type PI3Kα and therefore is considered an on-target toxicity for alpelisib. In addition to causing dose-limiting toxicity, systemic glucose-insulin feedback caused by inhibiting wild-type PI3K results in elevated insulin that can activate PI3K signaling and subsequently limit the efficacy of PI3K inhibitors. While these factors limit the clinical utility of alpelisib, these data nonetheless establish mutant PI3Kα as a clinically validated target in breast cancer. Because these toxicities result in suboptimal doses and dosing schedules that result in incomplete PI3Kα inhibition, we believe that a H1047X or E542/E545K mutant selective inhibitor will enable improved target inhibition, and therefore improved clinical efficacy. Additionally, overcoming hyperinsulinemia and hyperglycemia could increase efficacy by preventing insulin feedback that activates PI3K signaling.

Our solution, mutant selective inhibition of PI3Kα

Given the existence of mutations in PI3Kα with different biological mechanisms underlying aberrant activity, we believe there are multiple opportunities to develop distinct mutant selective inhibitors of PI3Kα. Addressing the challenge of mutant selectivity required us to express and then solve the structure of the full-length PI3Kα protein. This structure, which to our knowledge had previously not been solved, represented a technical challenge because PI3Kα is a membrane-bound protein. This type of protein is typically difficult both to purify in large quantities and to crystallize. Nonetheless, we were able to obtain the structure of full-length PI3Kα using Cryo-EM. The three-dimensional structure of PI3Kα was determined by collecting data from two-dimensional electron microscopic projections of thin layers of protein. The resulting three-dimensional protein structure provided us with fundamental insights into the mechanism of activation of PI3Kα and the impact of mutations on its function. Through the integration of these structural insights with a combination of experimental and computational techniques, our aim is to develop a franchise of mutant selective PI3Kα inhibitors. The first lead molecule derived from these efforts, which is focused on H1047X, is described below.

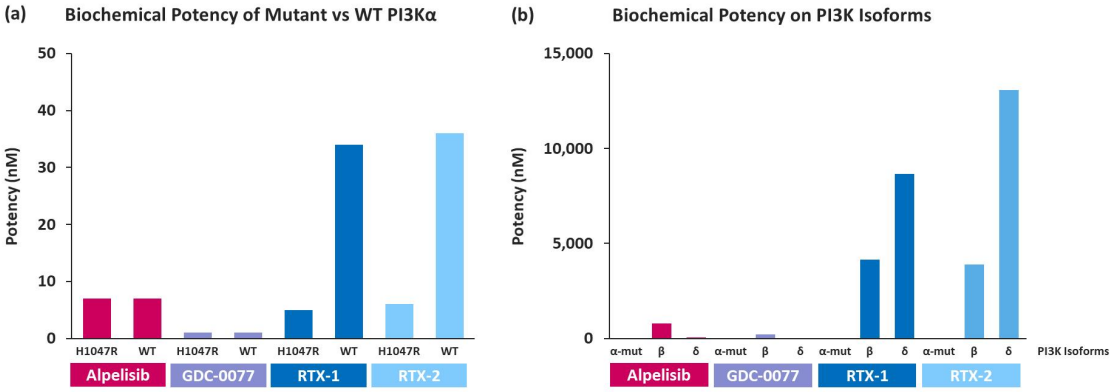
Current lead molecules for PI3K-H1047X Mutations, RTX-1 and RTX-2

RLY-PI3K1047 encompasses our lead small molecule inhibitors of PI3Kα, RTX-1 and RTX-2, that we designed to specifically target PI3Kα H1047X mutant via a previously undescribed allosteric mechanism. As described above, adverse events such as hyperglycemia are common among PI3K inhibitors that have been tested in the clinic, leading us to focus on identifying an inhibitor that bound to a novel site on PI3Kα. Our intent was to obtain a molecule that could selectively bind to the mutant form of PI3Kα.

Structural analyses of PI3Kα showed that mutations at amino acid H1047 cause structural alterations that are located away from the catalytic site, the place where other PI3K inhibitors bind. We then performed long timescale molecular dynamics simulations of wild-type and H1047R mutant PI3Kα to identify a series of dynamic structural changes caused by the mutation that are not present in the wild-type protein.

Utilizing this structural information, we designed inhibitors to target a novel allosteric binding site on the PI3Kα H1047R mutant protein that our computational and experimental approaches exposed. This process led to the discovery of RTX-1 and RTX-2, which are approximately 5-10-fold selective for the H1047R mutant form of PI3Kα compared to the wild-type protein in biochemical assays (**Figure 29**). In contrast, alpelisib and GDC-0077 (an orthosteric PI3Kα inhibitor currently in development) biochemically inhibited the mutant and wild-type proteins with approximately equivalent potency. In addition, we found that RTX-1 and RTX-2 are selective for PI3Kα over other PI3K isoforms, including PI3Kß and PI3Kδ, showing no measurable inhibition. In contrast, alpelisib and GDC-0077 inhibited the PI3Kδ isoform with IC50 < 1μM. Given toxicities associated with inhibitors that target PI3K isoforms other than PI3Kα and GDC-0077, including gastrointestinal side effects and transaminitis, we believe that these molecules provide a dual advantage of isoform and mutant selectivity, which could result in increased clinical efficacy compared alpelisib or other orthosteric PI3Kα inhibitors.

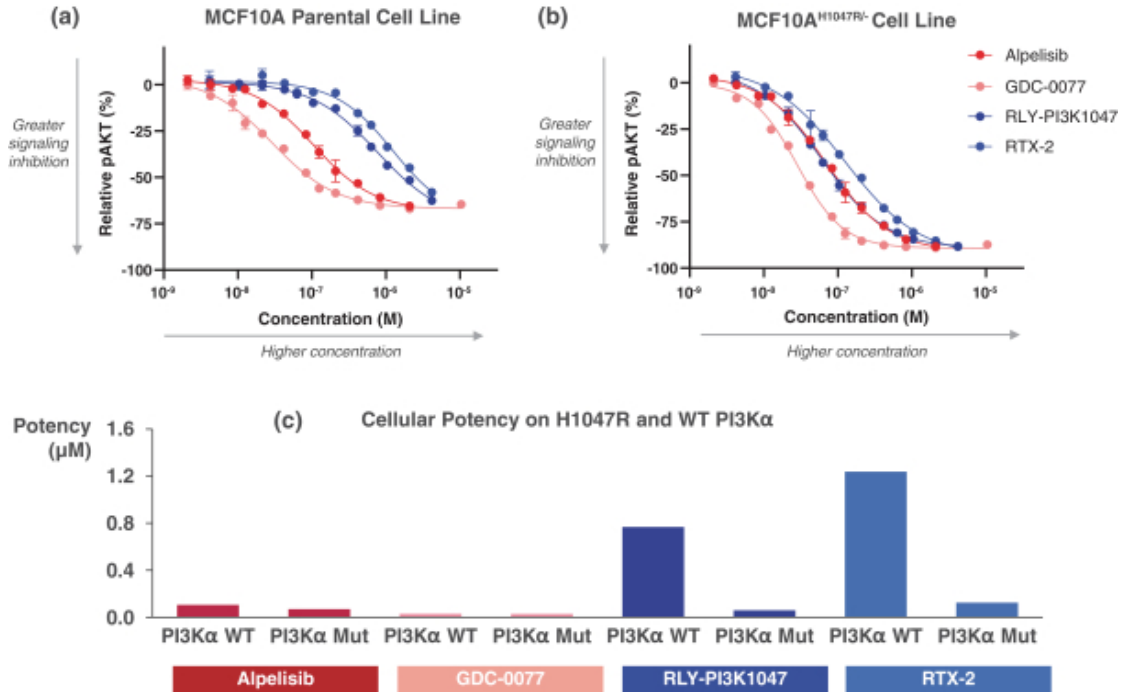
Figure 29: Compared to alpelisib and GDC-0077, RTX-1 and RTX-2 are more selective for the PI3Kα mutant (H1047R) compared to wild-type (a) and more selective for the PI3Kα isoform compared to other PI3K isoforms PI3Kß and PI3Kδ (b).



*Biochemical potency for RLY-PI3K1047 compared to alpelisib and GDC-0077. IC50 values are shown for inhibition of the PI3Kα mutant (H1047R) compared to wild-type **(a)** and for PI3Kα compared to other PI3K isoforms **(b)**. Phosphotransfer activity (PtdIns(3,4,5)P3 production in liposomes using diC8-PtdIns(4,5)P2 as a substrate in the presence of 100uM ATP and titrated compounds after a 120min incubation) was measured by ADP-Glo. All samples were run in duplicate and data represent the mean.*

This increased biochemical potency for PI3Kα H1047R mutant protein translates into an increased potency in cellular pharmacodynamic assays. RTX-1 was approximately 10-fold more potent for inhibition of phosphorylated AKT (pAKT), a key substrate of PI3Kα, in transformed breast epithelial cells expressing PI3Kα H1047R compared to the same cells expressing wild-type PI3Kα. RTX-2, an example of another lead compound generated in this program, also showed approximately 10-fold increased potency for inhibition of pAKT in transformed breast epithelial cells expressing PI3Kα H1047R (**Figure 30**). In contrast, alpelisib and GDC-0077 (an orthosteric PI3Kα inhibitor currently in development) showed approximately equal potencies in cells expressing either the mutant or wild-type forms.

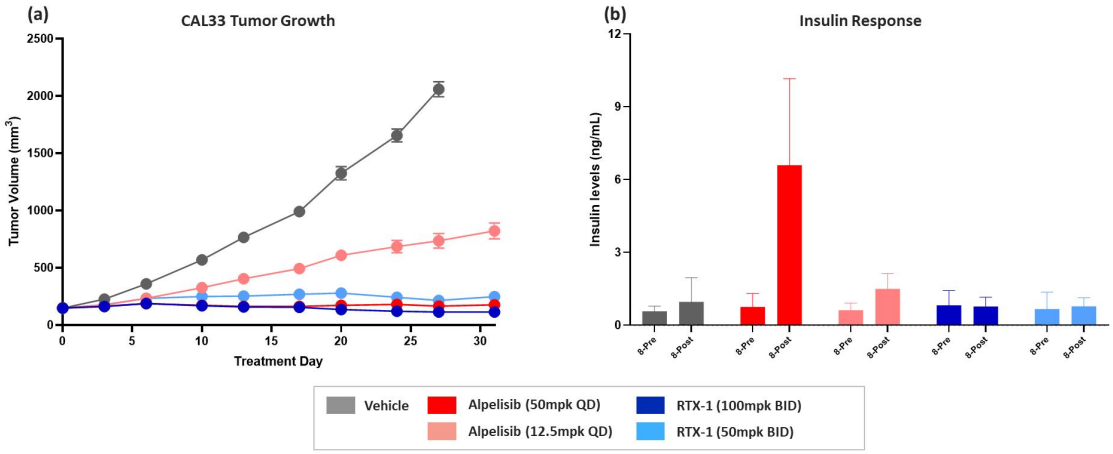
Figure 30: Compared to other clinical PI3Kα inhibitors (alpelisib and GDC-0077), Relay compounds more potently inhibits pAKT in cells expressing H1047R mutant PI3Kα compared to cells expressing wild-type PI3Kα.



*Inhibition of pAKT by Relay compounds RLY-PI3K1047 and RTX-2 in a pharmacodynamic assay. MCF10A immortalized breast epithelial cells endogenously expressing wild-type PI3Kα **(a)** or engineered to express the PI3Kα H1047R mutation **(b)** were treated with alpelisib, GDC-0077 or Relay compounds. After 2 hours cell lysates were collected and the impact on pAKT levels was assessed using an HTRF assay (three fold dilution dose response was run in duplicate, data represented as mean +/- standard error of the mean). Half maximal effective concentrations (EC50) from the dose response curves (a, b) are plotted in **(c)**.*

The selectivity of RTX-1 was then evaluated *in vivo*. Oral dosing of RTX-1 resulted in tumor growth inhibition in a mouse xenograft model of PI3Kα H1047R carcinoma at doses of 100 mg/kg delivered once or twice daily or 50 mg/kg delivered twice daily. (**Figure 31**). An important validation of our efforts to avoid the dose-limiting toxicities associated with other PI3K inhibitors is the effect of RTX-1 on hyperinsulinemia. As discussed above, hyperinsulinemia and hyperglycemia can lead to decreased efficacy of PI3K inhibitors. In a study evaluating the effects of alpelisib or RTX-1 treatment on insulin levels, RTX-1 led to minimal changes in serum insulin ($p=0.116$ compared to vehicle by 2-way ANOVA) when administered orally at all doses tested for the duration of the study. In contrast, alpelisib treatment resulted in increases in serum insulin ($p<0.0001$ compared to vehicle by 2-way ANOVA). Additionally, in an oral glucose tolerance test (OGTT) assessing insulin response after dosing of compounds, alpelisib treatment at 50 mg/kg once daily lead to larger increases in serum insulin compared to all doses of RLY-PI3K1047 tested ($p<0.0001$ by 2-way ANOVA).

Figure 31: RTX-1 inhibits tumor growth in vivo with minimal increases in serum insulin levels.



Anti-tumor activity and impact on serum insulin levels in response to treatment with RTX-1.

(a) *The CAL33 xenograft model was dosed once or twice daily (12 hour interval) with RTX-1 by oral administration or alpelisib once daily by oral administration, and tumor growth was evaluated. Data represent mean tumor volume over time, and error bars represent standard error of the mean. (n=8 per group).*

(b) *Insulin levels in serum were measured one hour before and one hour after drug administration in non-tumor bearing animals throughout an 8 day dosing period (measurements were taken specifically on day 1, 3, 5 and 8, n=8 per group). Data presented as mean +/- standard error of the mean.*

While RTX-1 is one lead molecule generated in this franchise, we are continuing lead optimization to identify mutant selective inhibitors of PI3Kα meeting our criteria to enter IND-enabling studies.

Our clinical development plan

We expect to begin IND-enabling studies for a differentiated PI3Kα H1047X mutant-selective inhibitor in 2021. With this profile, we will look to advance a precision medicine program that quickly establishes safety, tolerability, and preliminary efficacy, in patients with advanced solid tumors with H1047X mutations. Upon completion of dose escalation, the mutant PI3Kα inhibitor will be tested as a monotherapy in advanced cancer patients with PI3Kα H1047X mutations in a tumor-agnostic study. We will also pursue disease-specific development paths including combination with endocrine therapy +/- CDK4/6 inhibitors in hormone-receptor positive breast cancer and a PI3Kα H1047X mutation.

RLY-1971, an inhibitor of SHP2

Overview

RLY-1971 is designed to be an oral, small molecule inhibitor of the protein tyrosine phosphatase SHP2 that binds and stabilizes SHP2 in its inactive conformation. SHP2 promotes cancer cell survival and growth through the RAS pathway by transducing signals downstream from RTKs. Additionally, activating SHP2 mutations result in enhanced signaling in the absence of ligand stimulation and has been identified as oncogenic drivers in a range of tumors. As a critical signaling node and regulator, SHP2 drives cancer cell proliferation and plays a key role in the way cancer cells develop resistance to targeted therapies. We believe that inhibition of SHP2 could block a common path that cancer cells exploit to avoid killing by other antitumor agents, thus overcoming or delaying the onset of resistance to those therapies. We are currently evaluating the safety and tolerability of RLY-1971 in a Phase 1 dose escalation study in patients with advanced or metastatic solid tumors. In December 2020, we entered into the Genentech Agreement, a global collaboration and license agreement with Genentech for the clinical development and commercialization of RLY-1971. Given the range of cancers that are related to SHP2 dependence, we believe RLY-1971 has the potential to serve as a combination backbone therapy.

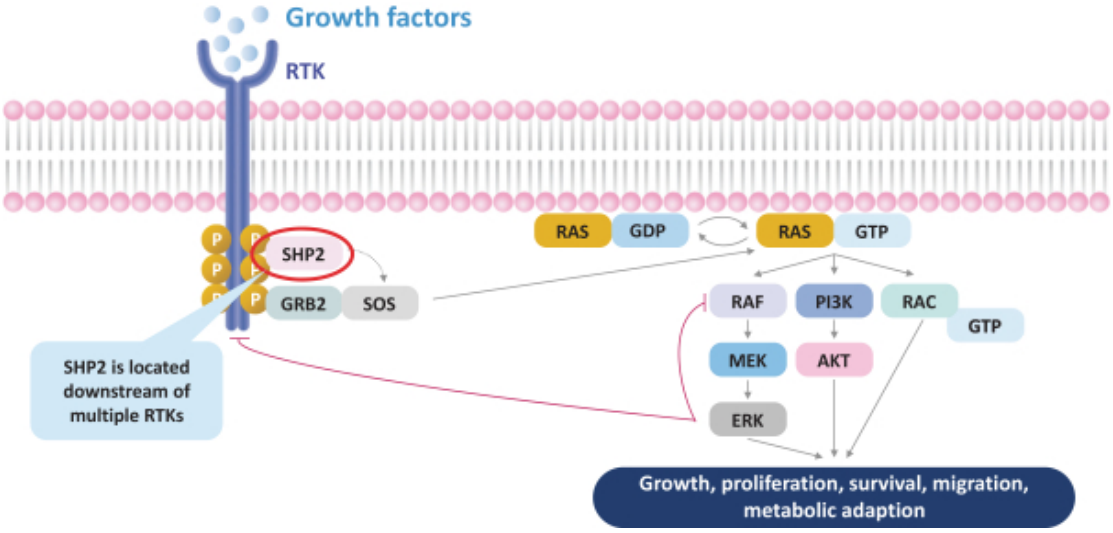
We estimate there are approximately 55,000 late-line patients annually in the United States with advanced lung cancer who might benefit from a combination of RLY-1971 with another targeted inhibitor. In the future, if RLY-1971 advances to earlier lines of combination treatment for lung cancer, we believe it could be applied in the treatment of approximately 90,000 patients annually in the United States. The subset of patients with KRAS ^{G12C} mutations in lung cancer that could potentially benefit from the combination of RLY-1971 with GDC-6036 is approximately 15,000-25,000 annually in the United States.

SHP2: a central regulator of cell signaling

SHP2 is a protein tyrosine phosphatase that plays a critical role in the transduction of intracellular signals downstream from RTKs, promoting cell survival and growth through the RAS pathway. SHP2 was the first phosphatase identified as a recurrently mutated oncogene, providing genetic support for the importance of SHP2 activation in promoting cancer. In addition to the central role of SHP2 in RTK signaling, some alterations in the RAS signaling pathway amplify signals transmitted by SHP2 and can therefore be suppressed by SHP2 inhibition. These include specific mutant forms of RAS (KRAS ^{G12C} and KRAS ^{G12A}), genomic amplification of wild-type KRAS, loss-of-function mutations in NF1, and class 3 mutations in BRAF. Consequently, there are multiple cancer genetic contexts where SHP2 inhibition could be beneficial as a monotherapy.

A key feature of SHP2 as an oncology target is its ability to regulate cell signaling that arises from multiple RTKs (**Figure 7**). Therapies targeted to these RTKs, and therapies targeting downstream nodes such as PI3K, KRAS and MEK, are often unable to durably inhibit tumor growth because these tumors are able to bypass the targeted RTK and shift growth factor signaling to an alternate RTK, rendering them less sensitive to the targeted therapy. This is generally referred to as bypass resistance. Because SHP2 regulates the activity of multiple RTKs, inhibition of SHP2 is an effective way to overcome bypass resistance as confirmed by cellular and animal model experiments. Indeed, added benefit of SHP2 inhibition has been demonstrated pre-clinically in combination with multiple agents, such as those targeting MEK, KRAS^{G12C}, EGFR, and ALK. We believe our SHP2 inhibitor has the potential to become a commonly used combination partner with multiple targeted therapies including those in our own pipeline.

Figure 7: SHP2 regulates the activity of multiple receptor tyrosine kinases (RTKs).

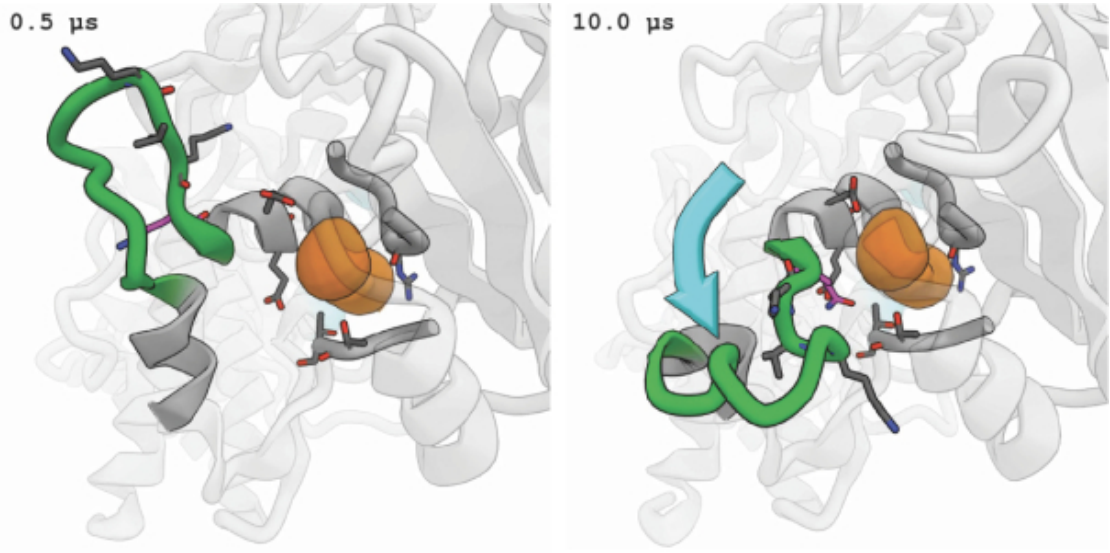


Our solution, RLY-1971

RLY-1971 is a small molecule inhibitor of SHP2 that binds and stabilizes SHP2 in its inactive conformation.

We utilized a combination of experimental and computational techniques to identify unique inhibitors. For example, using long timescale MD simulations we were able to understand changes in the dynamics of the binding pocket over time that would not have been appreciated with shorter timescale simulations (**Figure 8**). Informed by high-resolution room-temperature X-ray crystallographic data, we created a virtual representation of our lead molecule bound to the SHP2 protein. We then simulated this system over long timescales. As shown in Figure 8, we observed that a loop (green) to the left of the small molecule (orange) moves down towards the molecule over the course of the simulation. Our medicinal chemists were then able to leverage this understanding in their designs to create an inhibitor of SHP2. Importantly, this loop cannot be resolved using conventional X-ray crystallography. Therefore, relying on standard techniques could deprive medicinal chemists of a critical insight as they attempt to design improved compounds.

Figure 8: We depict a small molecule docked in a representation of the SHP2 protein where there is a green loop visible to the left of the small molecule (orange). A 500 ns MD simulation (0.5 µs) shows that the green loop is far away from the small molecule (left). A longer simulation (10.0 µs), reveals that the loop flips downwards, close to where the small molecule binds (right).



We then prioritized compounds with the best predicted binding to SHP2 over a 10 µs molecular dynamics simulation and tested the most stable compounds in our biochemical assay. This enabled filtering and prioritization of candidate molecules, resulting in the identification of RLY-1971, our clinical-stage compound. RLY-1971 inhibits SHP2 phosphatase activity (750 pM IC_{50}) in a biochemical assay designed to monitor dephosphorylation of a probe substrate. RLY-1971 also inhibits SHP2 in cellular assays, as measured by inhibition of ERK1/2 phosphorylation at Thr202/Tyr204 (1.3 nM IC_{50} in KYSE-520, an EGFR amplified gastric cancer cell line), and by inhibition of cancer cell proliferation (70 nM IC_{50} in KYSE-520 and 11 nM IC50 in NCI-H358, a $KRAS^{G12C}$ mutant NSCLC cell line) (**Figure 9**).

Figure 9: RLY-1971 potently inhibits SHP2 in biochemical and cellular assays.

Biochemical IC_{50}*	Cellular PD (pERK)**	Cellular Proliferation IC_{50}	
		NSCLC NCI-H358***	Gastric KYSE-520****
WT SHP2	KYSE-520	$KRAS^{G12C}$	EGFR amplification
0.75 nM	1.3 nM	11.0 nM	70.0 nM

RLY-1971 shows minimal inhibition of targets other than SHP2. RLY-1971 has bioavailability suitable for oral dosing, is metabolically stable, and demonstrates favorable pharmacokinetic properties in preclinical *in vivo* models. We do not predict that RLY-1971 will have significant drug-drug interactions based on weak inhibition of drug metabolizing enzymes. It is readily synthesized in bulk, can be formulated for oral delivery, and was well-tolerated in animal models.

We believe the key differentiating features of RLY-1971 from other SHP2 inhibitors in clinical development are:

- Chemical distinctiveness: it is chemically distinct from other SHP2 inhibitors in clinical development
- Potency: demonstrated 750 pM IC_{50} inhibition of SHP2 phosphatase in biochemical assays

- Dosing potential: projections of human pharmacokinetics suggest RLY-1971 will be amenable to continuous once daily dosing at relatively low active doses

RLY-1971 monotherapy pre-clinical experience

SHP2 inhibition has been shown in third party studies to result in tumor stasis or regression in preclinical xenograft models of tumors harboring KRAS genomic amplification, $KRAS^{G12C}$ mutations, $NF1^{LOF}$ mutations, or $BRAF^{Class3}$ mutations. Consistent with these findings, in our internal pre-clinical studies, RLY-1971 inhibited the proliferation of a panel of cancer cell lines driven by KRAS mutations that require signals transmitted by SHP2 ($KRAS^{G12C}$ and $KRAS^{G12A}$) but was inactive in cancer cell lines driven by other KRAS mutations that do not require SHP2 signals ($KRAS^{G12D}$) (**Figure 10**).

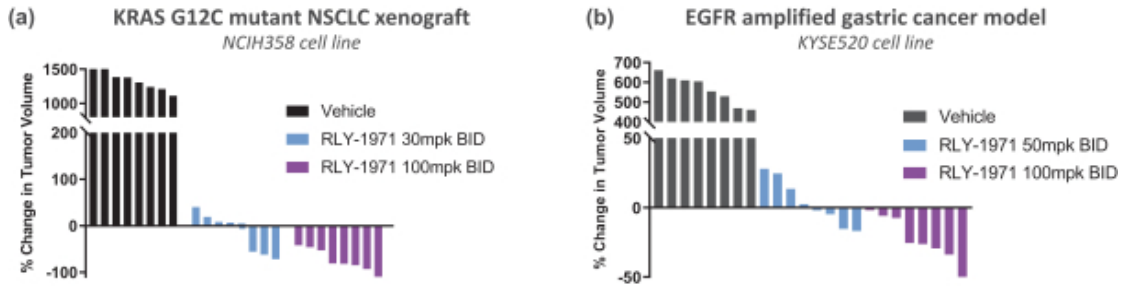
Figure 10: Inhibition of proliferation by RLY-1971 in cancer cell lines driven by KRAS mutations. Mutations that require SHP2 signals are potently inhibited by RLY-1971, whereas mutations that do not require SHP2 signals are insensitive to RLY-1971.

	Cell Line		Indication	RLY-1971 IC50 (nM)
SHP2 dependent	KRAS G12C	MIAPACA2	PDAC	3
		NCIH358	Lung	11
		SW1573	Lung	18
		NCIH23	Lung	43
		SW1463	Colon	15
		SW837	Colon	19
	KRAS G12A	NCIH1573	Lung	14
		RERFLCAD1	Lung	14
Non-SHP2 dependent	KRAS G12D	A427	Lung	1230
		SKLU1	Lung	10000
		HCC1588	Lung	10000

A panel of $KRAS^{G12}$ mutant cancer cell lines were grown in 3D spheroids and treated with RLY-1971 in a proliferation assay. $KRAS^{G12C}$ and $KRAS^{G12A}$ mutations retain intrinsic GTPase activity and therefore require SHP2 signaling, whereas the $KRAS^{G12D}$ mutation does not. For cell lines indicated, cells were plated at a density of 2000 cells/well in round bottom ultra-low attachment 384-well plates (Corning) in growth media and cells are allowed to form three-dimensional structures at 37°C, 5% CO2 incubator for 48 hours. After a 48 hour incubation period, cells were then treated in triplicate with serial 3-fold dilutions of inhibitor in complete growth media and cells were returned to incubator for an additional 120 hours. CellTiter-Glo 3D reagent (Promega) was then added into each well and incubated are room temperature for 30 minutes followed by reading on an EnVision Reader (Perkin Elmer) using standard conditions. Assay data was normalized to DMSO control wells. Dose response curve fitting and IC50 values were determined using Genedata analyzer.

To demonstrate activity of RLY-1971 as a single agent *in vivo*, we tested it in multiple cancer xenograft mouse models. Consistent with our *in vitro* data and the role of SHP2 as a critical mediator of RTK signaling, we observed that RLY-1971 induced regression in cancer xenograft models harboring a KRAS^{G12C} mutation or genomic amplification of EGFR when administered on a continuous dosing schedule (**Figure 11**).

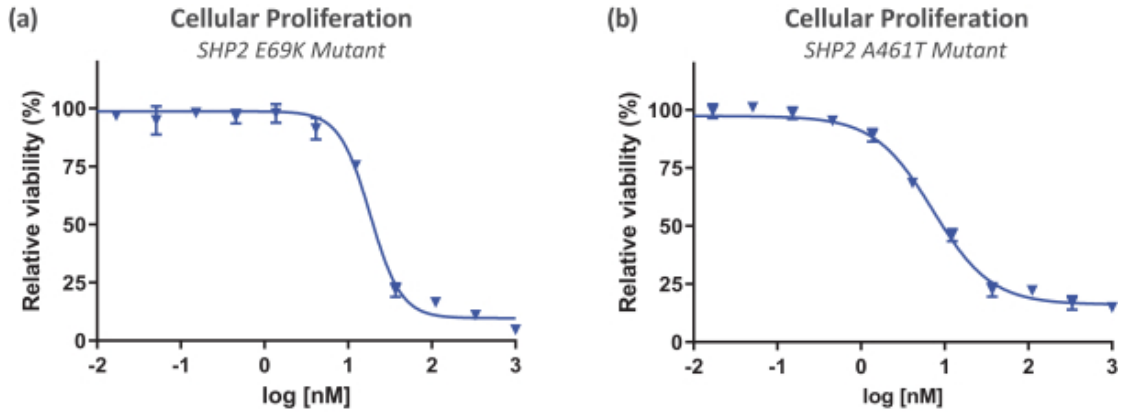
Figure 11: RLY-1971 induces regression in KRAS ^{G12C} mutant and EGFR amplified cancer xenograft models.



*Anti-tumor activity of the SHP2 inhibitor RLY-1971 dosed twice daily by oral administration (PO BID) in **(a)** the KRAS ^{G12C} mutant NSCLC xenograft model NCIH358 after 28 days on treatment and **(b)** the EGFR amplified gastric cancer xenograft model KYSE-520 after 21 days on treatment. Treatment with RLY-1971 resulted in dose-dependent anti-tumor activity and regression in both models. Data represent waterfall plots of individual end of study tumors, with tumor volume expressed as percentage change relative to initial tumor volume. Each animal is represented as a separate bar (number of mice per group = 8). For each of the studies the statistical difference between the vehicle treated and RLY-1971 treated groups was assessed by one-way analysis of variance (ANOVA). In both studies the RLY-1971 treated groups were determined to be significantly different than the vehicle treated group with a P value < 0.001.*

In addition, RLY-1971 inhibited the proliferation of cancer cell lines engineered to express known cancer mutations in SHP2 (**Figure 12**). These mutations bias SHP2 towards an open, active conformation in direct opposition to the allosteric inhibition effected by RLY-1971. RLY-1971 retains nanomolar potency against activating mutations of SHP2. We hypothesize that the activity of RLY-1971 against activating mutations of SHP2 could result in more durable benefit by suppressing the emergence of resistant cell populations with SHP2 resistance mutations.

Figure 12: RLY-1971 inhibits the proliferation of cells expressing known SHP2 activating mutations.



*Inhibition of proliferation by RLY-1971 in TF1 cancer cells expressing known cancer mutations in SHP2. TF1 cells were engineered to express the SHP2 mutations **(a)** E69K (IC50 = 18.4 nM) or **(b)** A461T (IC50 = 7 nM) and*

treated with RLY-1971 in a proliferation assay. 500 cells/well were seeded in round bottom ultra-low attachment 384-well plates (Corning) in growth media and incubated for 48 hours at 37°C in 5% CO2. Cells were then treated in triplicate with serial 3-fold dilutions of inhibitor in growth media. Following incubation in the presence of compound for an additional 120 hours, cell viability was determined using the CellTiter-Glo 3D assay kit (Promega) following the manufacturer's instructions. Luminescence was read in an EnVision Multimode Plate Reader (Perkin Elmer). Assay data was normalized to DMSO values, and dose response curve fitting was performed using Genedata analyzer.

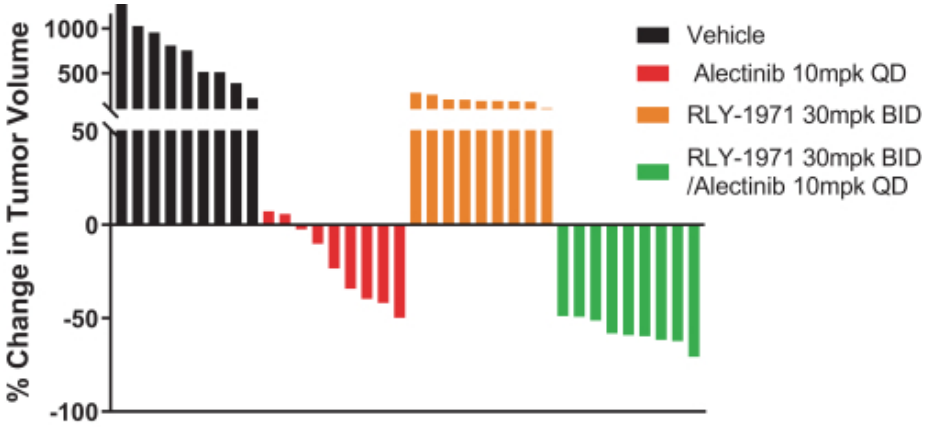
RLY-1971 as a combination therapy

Given the role of SHP2 in mediating bypass resistance, we believe that SHP2 inhibitors have significant therapeutic potential when given in combination with other targeted therapies. Due to the increased potency and broader mutational coverage of next-generation targeted therapies, lower rates of on-target resistance have been observed in the clinic, with a greater number of patients progressing due to bypass resistance. An example of this is seen with EGFR inhibitors, where first-generation inhibitors (erlotinib and gefinitib) have greater on-target resistance compared to a third-generation inhibitor (osimertinib). As SHP2 is involved in signaling for numerous oncogenes, including EGFR, $KRAS^{G12C}$, ALK and MET, combination therapy with RLY-1971 represents a potential significant therapeutic opportunity.

Consistent with the role of SHP2 in RTK signaling in NSCLC, in our pre-clinical experiments, RLY-1971 demonstrated combination benefit in cell culture experiments when co-administered with inhibitors of MEK, ALK, or EGFR.

To demonstrate combination benefit with our SHP2 inhibitor *in vivo*, we combined RLY-1971 with the ALK inhibitor alectinib in an ALK-translocated NSCLC xenograft mouse model (NCIH3122) that was derived *in vitro* to have reduced sensitivity to ALK inhibition (**Figure 13**). DNA sequencing did not reveal new ALK mutations in the cell line. Therefore, these cells likely have reduced sensitivity due to a bypass mechanism. The combination of RLY-1971 with alectinib resulted in tumor regressions in all treated animals.

Figure 13: Anti-tumor activity of RLY-1971 and the ALK inhibitor alectinib as single agents or in combination in an ALK translocated NSCLC xenograft model (NCI-H3122) derived *in vitro* to have reduced sensitivity to ALK inhibition.



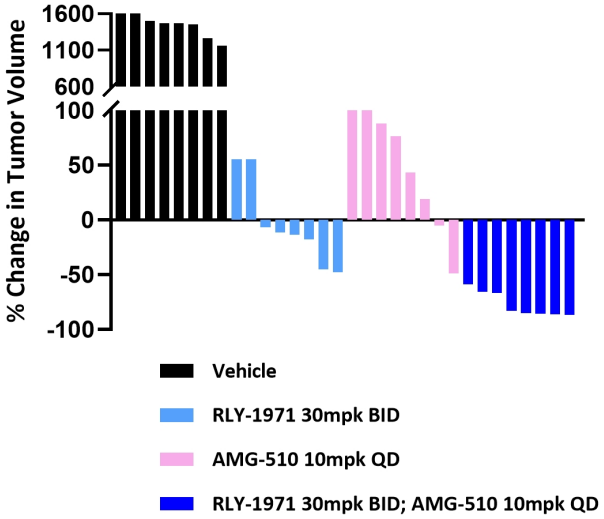
Daily oral administration of RLY-1971 at 30mpk BID in combination with alectinib at 10mpk QD (green) resulted in increased efficacy compared to alectinib at 10mpk QD (red) or RLY-1971 at 30mpk BID (orange) alone in an ALK translocated NSCLC xenograft model (NCI-H3122) derived in vitro to be less sensitive to ALK inhibition. Data represent waterfall plots of individual tumors after 27 days of treatment with compounds, with tumor volume expressed as percentage change relative to initial tumor volume. Each animal is represented as a separate bar

(number of mice per group = 9). The statistical difference between the combination treated group and the RLY-1971 or alectinib single agent groups was assessed using an unpaired t-test. The combination treated group with significant with P-value <0.001 compared to either single agent group.

In addition to RTK inhibitors, combination benefit for SHP2 inhibition has been demonstrated with other targeted agents including MEK inhibitors and KRAS^{G12C} inhibitors in cancer xenograft models harboring KRAS^{G12C} mutations or KRAS amplifications. The efficacy of direct KRAS^{G12C} inhibition may be limited by adaptive feedback reactivation of the RAS-MAPK pathway through upregulation of multiple RTKs. Activation of these RTKs leads to compensatory activation of wild-type RAS isoforms, which cannot be inhibited by KRAS^{G12C}-specific inhibitors, thus leading to resistance. SHP2 is unique in that it transmits signals from multiple RTKs and is therefore critical in mediating feedback reactivation of the RAS pathway during KRAS^{G12C} inhibition.

Consistent with these observations, RLY-1971 demonstrated *in vivo* combination benefit with the KRAS^{G12C} specific inhibitor AMG-510 in a KRAS^{G12C} lung cancer xenograft model (**Figure 14**). Specifically, the combination resulted in regression in all animals, whereas each single agent resulted in more modest activity at the doses that were tested. These results suggest that SHP2 inhibition abrogates compensatory RAS-MAPK pathway activation during KRAS^{G12C} inhibition. Molecular characterization of phosphorylated-ERK, or Perk, a downstream marker of RAS-MAPK pathway activity, supports this conclusion. *In vitro*, the combination of RLY-1971 and the KRAS^{G12C} -specific inhibitor ARS-1620 was able to fully suppress pERK in this model, while each inhibitor individually only partially suppressed pERK. Based on these data, we believe that the combination of RLY-1971 with KRAS^{G12C} -specific inhibitors warrants clinical studies in patients with tumors harboring KRAS^{G12C} mutations.

Figure 14: RLY-1971 and the KRAS^{G12C}-specific inhibitor AMG-510 demonstrate synergy when used in combination in the KRAS^{G12C} NCI-H358 lung cancer cell line.



In vivo combination benefit of RLY-1971 and the KRAS^{G12C}-specific inhibitor AMG-510. Anti-tumor activity of the SHP2 inhibitor RLY-1971 dosed twice daily (BID) by oral administration at 30 mpk and the KRAS ^{G12C} inhibitor AMG-510 dosed once daily (QD) by oral administration at 10 mpk in the KRAS ^{G12C} mutant NSCLC xenograft model NCIH358. Treatment with the combination resulted in regression in all animals. Data represent waterfall plots of individual end of study tumors, with tumor volume expressed as percentage change relative to initial tumor volume. Each animal is represented as a separate bar (number of mice per group = 8)

In addition to the therapeutic opportunity associated with combining with other targeted therapies, we believe RLY-1971 has the potential to be a combination partner with the product candidates in our own precision oncology portfolio, RLY-4008 and RLY-PI3K1047.

Our clinical development plan

In the first quarter of 2020, we began evaluating the safety and tolerability of RLY-1971 in a first-in-human dose escalation study in patients with advanced or metastatic solid tumors. The primary objectives are to determine the maximum tolerated dose (MTD)/recommended phase 2 dose (RP2D), and to define the overall safety profile of RLY-1971. Secondary objectives are to assess the pharmacokinetics, pharmacodynamics, and to explore preliminary anti-tumor activity of RLY-1971. Patients will receive RLY-1971 administered orally, once daily. Once daily oral dosing was selected based on projected human pharmacokinetics and exposures calculated from multi-species pharmacokinetics and allometric scaling.

The first-in-human monotherapy data will facilitate subsequent clinical evaluation and development of RLY-1971 in combination with other targeted therapies in indications where SHP2 inhibition may exert synergistic antitumor effects. Future development for RLY-1971 will be governed by a joint development team between us and Genentech. We expect a combination trial of RLY-1971 and Genentech's KRAC G12C inhibitor, GDC-6036, to be initiated in 2021.

Our Discovery Programs

We are deploying our Dynamo platform to advance an additional three discovery-stage precision oncology programs. As with our lead programs, these programs leverage insights into protein conformational dynamics to address high-value, genetically validated oncogenes that previously have been intractable to conventional drug-discovery approaches. The capabilities for our Dynamo platform in protein visualization can be applied to multiple therapeutic areas beyond precision oncology. We are continuing to leverage the power of our Dynamo platform to further diversify our pipeline by extending our approach to address genetically validated targets in monogenic diseases with two discovery-stage programs, where genetic alterations lead to disease-causing defects in protein conformational dynamics.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid innovation of new technologies, fierce competition and strong defense of intellectual property. While we believe that our platform and our knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

We compete in the segments of the pharmaceutical, biotechnology, and other related markets that address experimentally and computationally driven structure-based drug design in cancer and genetic diseases. There are other companies focusing on structure-based drug design to develop therapies in the fields of cancer and other diseases. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. 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 from segments of the pharmaceutical, biotechnology and other related markets that pursue precision medicines. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products.

We believe principal competitive factors to our business include, among other things, the rich protein structural data sets we are able to generate, the power and accuracy of our computations and predictions, ability to integrate experimental and computational capabilities, ability to successfully transition research programs into clinical development, ability to raise capital, and the scalability of the platform, pipeline, and business.

While there are many pharmaceutical and biotechnology companies that use some of the same tools that we use in our platform, we believe we compete favorably on the basis of these factors. The effort and investment required to develop a highly integrated experimental and computational platform similar to ours will hinder new entrants that are unable to invest the necessary capital and time and lack the breadth and depth of technical expertise required to develop competing capabilities. Our ability to remain competitive will largely depend on our ability to continue to augment our integrated experimental and computational platform and demonstrate success in our drug discovery efforts.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

In addition, we will need to develop our product candidates in collaboration with diagnostic companies, and we will face competition from other companies in establishing these collaborations. Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

RLY-4008

While there are currently no approved products that selectively target FGFR2, we are aware of other companies developing therapeutics that selectively target FGFR2, including, but not limited to, Five Prime Therapeutics and Russian Pharmaceutical Technologies. Specifically, we expect RLY-4008 to compete with approved development stage non-selective inhibitors of the FGFR receptor family that are being tested in patients with FGFR2 alterations, including but not limited to, Incyte Corporation (pemigatinib), QED Therapeutics (infigratinib), Basilea Pharmaceutica AG (derazantinib), Janssen Pharmaceuticals, Inc. (erdafitinib), Otsuka Holdings Co., Ltd. through its subsidiary Taiho Pharmaceutical Co., Ltd. (TAS-120), Debiopharm Group (Debio1347), Eisai Co., Ltd. (E-7090), and InnoCare Pharma Limited (ICP-192).

The development of RLY-4008 will focus on solid tumor patients with FGFR2 alterations, including intrahepatic cholangiocarcinoma (ICC) patients harboring FGFR2 gene fusions. While there are no approved systemic therapies for ICC, the current standard of care for unresectable or metastatic patients is first-line gemcitabine/cisplatin chemotherapy. In addition, there are other companies developing potentially competitive drug candidates in ICC including, but not limited to, Merck & Co, Astrazeneca plc, Merck KGaA, and NuCana plc.

Mutant-PI3Kα Inhibitor Program

We expect that our mutant-selective PI3Kα inhibitor program will compete against an approved drug, Piqray (alpelisib), a non-selective PI3Kα inhibitor marketed by Novartis for the treatment of PI3Kα mutated breast cancer.

We are aware of other companies developing therapeutics that target both wild-type and mutant PI3Kα, including, but not limited to, Roche Holding AG through its subsidiary Genentech, Petra Pharma Corporation, Menarini Group, Luoxin Pharma and Shanghai HaiHe Pharma Co. Petra Pharma Corporation also has a preclinical development program for a mutant-selective PI3Kα inhibitor.

RLY-1971

While there are currently no approved products targeting SHP2, we are aware of other companies in clinical trials developing therapeutics that target SHP2, including, but not limited to, Revolution Medicines in partnership with Sanofi S.A., Novartis International AG, Navire Pharma, Inc., Erasca, Inc. and Jacobio Pharmaceuticals, Inc. in partnership with AbbVie Inc.

Our Collaborations

Key Scientific Collaborations

While we have invested extensively in our in-house capabilities and know-how, we selectively work with key collaborators and field experts on certain emerging technologies. Most of our experimental collaborations are focused on the technologies we use to visualize protein structure at the atomic level. For example, we work with Professor James Fraser from UCSF on performing and analyzing room temperature X-ray crystallography experiments and Professor Adam Frost from UCSF on Cryo-EM image analysis. Both are world leading experts on these technologies, and they provide important know-how and insights in collaboration with our scientists.

Our key computational collaboration is with D. E. Shaw Research, LLC, or D. E. Shaw Research, a computational biochemistry research firm operating under the scientific leadership of Dr. David E. Shaw, which has developed proprietary software and hardware to perform long timescale molecular dynamics simulations. Through an affiliate, D. E. Shaw Research is also one of our investors. We collaborate with D. E. Shaw Research scientists to research certain protein targets on an exclusive basis, with a focus on the dynamic behavior of proteins, through the use of D. E. Shaw Research's computational modeling capabilities, such as the Anton 2 supercomputer and proprietary algorithms and software developed specifically by D. E. Shaw Research for processing long timescale molecular dynamics simulations. Our scientists work closely with D. E. Shaw Research scientists on each of our programs, especially in the discovery stage as we develop motion-based hypotheses and identify lead compounds. See "—License Agreements and Strategic Collaborations —Collaboration and License Agreement with D. E. Shaw Research, LLC" for more detail on the terms of the DESRES Agreement.

We also have other collaborations mostly focused on developing machine learning models. Specifically, we collaborate with Google on machine learning models to generate novel molecules with specific activity, and with Professor Tim Cernak from the University of Michigan on machine learning models focused on chemical synthesis and high throughput experimentation.

License Agreements and Strategic Collaborations

Collaboration and License Agreement with D. E. Shaw Research, LLC

On June 15, 2020, we entered into an Amended and Restated Collaboration and License Agreement with D. E. Shaw Research, extending the term and otherwise modifying the terms of a Collaboration and License Agreement originally entered into on August 17, 2016, as amended. We refer to this amended and restated agreement as the DESRES Agreement. Under the DESRES Agreement, we agreed to collaborate with D. E. Shaw Research to research certain biological targets through the use of D. E. Shaw Research computational modeling capabilities focused on analysis of protein motion, with an aim to develop and commercialize compounds and products directed to such targets. After completing the computational modeling with D. E. Shaw Research and naming a compound development candidate, we develop and commercialize such compounds and products. D. E. Shaw Research has no

involvement with the clinical development or potential commercialization of these compounds and products, regardless of any co-ownership rights pursuant to the terms of the DESRES Agreement, and instead receives solely milestone and royalty payments as described below.

Under the DESRES Agreement, there are three categories of targets: Category 1 Targets, Category 2 Targets and Category 3 Targets. We and D. E. Shaw Research agreed on a list of Category 1 Targets and Category 2 Targets as part of the DESRES Agreement. Category 1 Targets are targets that, among other things, we collaborate on with D. E. Shaw Research, D. E. Shaw Research has exclusivity obligations with respect to, and we may owe royalties on; Category 2 Targets are targets in connection with the potential re-categorization of which into a Category 1 Target, we may, among other things, perform in vitro non-clinical research and development (but not in vivo non-clinical development, clinical development or commercialization), and Category 3 Targets are all targets other than Category 1 Targets and Category 2 Targets. There are mechanisms for re-categorizing targets, and we and D. E. Shaw Research have re-categorized a number of targets during the first four years of our collaboration. Our rights and obligations, and D. E. Shaw Research's rights and obligations, with respect to targets vary by the category of each target. However, the parties only conduct collaborative activities together for Category 1 Targets, and we are limited to a maximum of eleven Category 1 Targets in the current collaboration year (with such number potentially changing from year to year, with any increase in such number of targets subject to the collaboration in each collaboration year capped at four more than the highest number of such targets in the previous year). The sum of the number of Category 1 Targets and the number of Category 2 Targets is capped at twenty, in any event.

Work product that is jointly developed with D. E. Shaw Research is initially co-owned with them. Specifically, intellectual property rights covering the composition of matter for RLY-1971 are currently co-owned by D. E. Shaw Research and us under this arrangement. We have the right to have patents claiming certain product candidates (including one claiming RLY-1971) assigned to us upon issuance of those patents. Although other compounds in our FGFR2 and PI3Kα programs were jointly conceived with D. E. Shaw Research, RLY-4008 and RLY-PI3K1047 were conceived solely by Relay Therapeutics inventors. For each Category 1 Target there is a limit of up to 10 core compounds and a total of 500 compounds including derivatives of those core compounds that can be designated as solely owned by us, provided that if D. E. Shaw Research provides us with notice that certain compounds cannot be designated as solely owned by us due to concerns in respect of a Category 3 Target, then the limit on Category 1 Target core compounds will increase by one and the limit on total compounds will increase by fifty, but subject to a maximum of 15 and 750, respectively, for each Category 1 Target. Each of we and D. E. Shaw Research grants to the other a perpetual, irrevocable, non-exclusive license for jointly held intellectual property, subject to certain exclusions.

During the initial research term, which is expected to last until August 2025, unless extended by mutual agreement, D. E. Shaw Research will not, and will cause its subsidiaries not to, research any Category 1 Target (or grant certain rights with respect to such target) with the aim of pursuing any compound designed to interact with or bind to such Category 1 Target, subject to some exceptions. Following the end of the initial research term, D. E. Shaw Research will not, and will cause its subsidiaries not to, research a Category 1 Target (or grant certain rights with respect to such target) with the aim of pursuing any compound designed to interact with or bind to any target that was a Category 1 Target at the end of the initial research term, subject to some exceptions. D. E. Shaw Research will not be bound by such exclusivity provisions with respect to a particular Category 1 Target if we, and parties acting on our behalf, stop using commercially reasonable efforts to research, develop or commercialize any products against such Category 1 Target. Further, D. E. Shaw Research will be released from such exclusivity obligations with respect to a particular Category 1 Target if, at least 24 months after the end of the initial research term, D. E. Shaw Research informs us that D. E. Shaw Research will forgo all future payments with respect to such Category 1 Target.

During the initial research term, neither D. E. Shaw Research nor we will, and we will each cause our subsidiaries not to, research a Category 2 Target (or grant certain rights with respect to such target) with the aim of pursuing any compound designed to interact with or bind to such Category 2 Target, subject to some exceptions. These exclusivity restrictions do not extend past the initial research term.

There is no exclusivity with respect to Category 3 Targets.

Through December 31, 2020, we have made cash payments to D. E. Shaw Research totaling $8.4 million in the aggregate. On a product-by-product basis, we have also agreed to pay D. E. Shaw Research milestone payments upon the achievement of certain development and regulatory milestone events for products we develop under the DESRES Agreement that are directed to a Category 1 Target or any target that was a Category 1 Target. Our SHP2, FGFR2 and PI3K programs are each directed to Category 1 Targets. Such payments for achievement of development and regulatory milestones total up to $7.25 million in the aggregate for each of the first three products we develop, and up to $6.25 million in the aggregate for each product we develop after the first three.

Additionally, we have agreed to pay D. E. Shaw Research, on a product-by-product basis, with respect to products directed to Category 1 Targets or any target that was a Category 1 Target, royalties in the low single digits on worldwide net sales of products that we commercialize directed to the targets selected for development under the DESRES Agreement, subject to certain reductions. Royalties are payable on a product-by-product and country-by-country basis until the later of twelve years after first commercial sale in such country or the expiration of all applicable regulatory exclusivities in such country. On a product-by-product basis, we also agreed to pay D. E. Shaw Research sales milestone payments up to $36.0 million in the aggregate based on sales of each product directed to a Category 1 Target or any target that was a Category 1 Target. Further, if we enter into transactions granting third parties rights to a Category 1 Target or a compound or product directed to a Category 1 Target or any target that was a Category 1 Target. such as our collaboration with Genentech for RLY-1971 discussed below, but subject to certain exclusions, we will share with D. E. Shaw Research a percentage of the proceeds of such transactions ranging from the low- to high-single digits, depending on the stage of development of compounds or products directed to such target at the time we enter into such transaction. We have also agreed to pay D. E. Shaw Research an annual collaboration fee in August of each year during the initial research term, such fee to be $7,900,000 for each year between 2020 and 2025.

Unless earlier terminated, the DESRES Agreement will continue at least until the end of the initial research term and thereafter on a target-by-target basis until all payment obligations have expired. D. E. Shaw Research has the right to terminate the DESRES Agreement due to non-payment. We and D. E. Shaw Research each have the right to terminate the DESRES Agreement due to an uncured material breach by the other party, or in the event the other party becomes insolvent or enters into bankruptcy or dissolution proceedings. Our payment obligations to D. E. Shaw Research survive termination of the DESRES Agreement. If D. E. Shaw Research terminates the DESRES Agreement, the exclusivity obligations will terminate. If we terminate the DESRES Agreement, D. E. Shaw Research remains bound by its exclusivity obligations with respect to certain targets until, on a target-by-target basis, there are no further payment obligations due to D. E. Shaw Research in respect of such targets.

Collaboration and License Agreement with Genentech

On December 11, 2020, we entered into a Collaboration and License Agreement with Genentech, Inc. and F. Hoffmann-La Roche Ltd, collectively referred to as Genentech. We refer to this agreement as the Genentech Agreement. Pursuant to the Genentech Agreement, we and Genentech will collaborate on the development and commercialization of RLY-1971.

Unless Genentech elects to exercise its option to conduct the remainder of the ongoing Phase 1a clinical trial for RLY-1971, we will complete this trial. Genentech will be responsible for conducting all subsequent clinical development of RLY-1971, including in any combination trials with Genentech's compound, GDC-6036, that directly binds to and inhibits KRAS ^{G12C}, or other compounds.

We retain the right to develop RLY-1971 or certain other small molecule inhibitors of SHP2 developed under the Genentech Agreement, or a Licensed Candidate, or pharmaceutical product containing a Licensed Candidate, or a Licensed Product, in combination with any of our compounds targeting FGFR2, including RLY-4008, or PI3Kα, including candidates in our RLY-PI3K1047 program, which we refer to as a Relay Combination Product. If we opt into the Profit/Cost Share described below, Genentech may share the development costs of any clinical trial for a Relay Combination Product.

Genentech has the sole right and responsibility to commercialize Licensed Products, in any and all combinations, except that we have the right to co-promote a Licensed Product solely as part of our commercialization of Relay Combination Products. Genentech will be solely responsible for all regulatory matters for all Licensed Candidates

and Licensed Products after the assignment by us to Genentech of all related regulatory materials, including the IND application for the Phase 1a Trial, other than with respect to Relay Combination Products.

Under the terms of the Genentech Agreement, we have received $75 million in an upfront payment and are eligible to receive $25 million in additional near-term payments.

We have the option, exercisable one time in our sole discretion, to fund half of the development costs of RLY-1971 in the United States and share half of the net profits or net loss of commercializing RLY-1971 in the United States, which we refer to as the Profit/Cost Share. If we opt into the Profit/Cost Share, we will also be eligible to receive up to an aggregate of an additional $410 million upon the achievement of specified commercialization and sales-based milestones for RLY-1971 outside of the United States and tiered royalties ranging from low-to-mid teens on annual net sales of RLY-1971 outside of the United States, on a country-by-country basis, subject to reduction in certain circumstances. At any time prior to the third anniversary of the first commercial sale of RLY-1971 in the United States, we may elect to opt-out of further participation in the Profit/Cost Share. If we elect to opt-out, then Genentech's milestone and royalty payment obligations will revert to the financial terms that would be applicable if we had not opted into the Profit/Cost Share as described below as of the effective opt-out date, with certain adjustments.

If we do not opt into the Profit/Cost Share, Genentech will be responsible for all development costs of RLY-1971 other than the costs incurred by us for the ongoing Phase 1a trial of RLY-1971, and we will be eligible to receive up to an aggregate of an additional $695 million upon the achievement of specified development, commercialization and sales-based milestones for RLY-1971 worldwide. We will also be eligible to receive tiered royalties ranging from low-to-mid teens on annual worldwide net sales of RLY-1971, on a country-by-country basis, subject to reduction in certain circumstances.

In the event of regulatory approval of both RLY-1971 and GDC-6036 in combination, we are eligible to receive additional royalties.

Under the Genentech Agreement, we granted an exclusive, worldwide, royalty-bearing license to Genentech, with the right to sublicense, to develop and commercialize RLY-1971. Between the parties, Genentech has the first right, but not the obligation, to file, prosecute and maintain any patents licensed to it pursuant to the Genentech Agreement, as well as to enforce infringement of or defend claims against such patents that relate to Licensed Candidates and Licensed Products. The parties will share any liabilities or damages arising from the enforcement of such patents or any third-party patent claims.

Other than with respect to Relay Combination Products and other activities in accordance with the Genentech Agreement, we may not, directly or indirectly, conduct any activities related to the research, development, manufacture or commercialization of any SHP2 inhibitor. During the first three years of the term of the Genentech Agreement, Genentech will cause its research and early development organization not to sponsor or conduct a registrational trial for a SHP2 inhibitor other than a Licensed Product.

Unless earlier terminated, the Genentech Agreement will remain in effect until the later of the date on which Genentech is no longer developing or commercializing RLY-1971 in the United States if we have opted into the Profit/Cost Share and have not subsequently opted-out, or the expiration of all Genentech's royalty payment obligations to us. The parties may terminate the Genentech Agreement for the other party's material breach or insolvency or, on a country-by-country basis, the failure to obtain merger control under applicable antitrust laws. Additionally, Genentech may terminate the Genentech Agreement for convenience, and we may terminate the Genentech Agreement for certain patent challenges by Genentech or if Genentech has not conducted any research, development, manufacturing or commercialization activities with respect to any Licensed Candidate or Licensed Product for a specified period.

Intellectual Property

We seek to protect the intellectual property and proprietary technology that we consider important to our business, including by pursuing patent applications that cover our product candidates and methods of using the same, as well as any other relevant inventions and improvements that we believe to be commercially important to the development of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. Our commercial success depends, in part, on our ability

to obtain, maintain, enforce and protect our intellectual property and other proprietary rights for the technology, inventions and improvements we consider important to our business, and to defend any patents we may own or in-license in the future, prevent others from infringing any patents we may own or in-license in the future, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid and enforceable patents and proprietary rights of third parties.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our pending provisional and PCT patent applications, and any patent applications that we may in the future file or license from third parties, may not result in the issuance of patents and any issued patents we may obtain do not guarantee us the right to practice our technology or commercialize our product candidates. We also cannot predict the breadth of claims that may be allowed or enforced in any patents we may own or in-license in the future. Any issued patents that we currently own or may own or in-license in the future may be challenged, invalidated, circumvented or have the scope of their claims narrowed. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide.

The term of individual patents depends upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier expiring patent. The term of a patent claiming a new drug product may also be eligible for a limited patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. The restoration period cannot be longer than five years, and the restoration period may not extend the patent term beyond 14 years from the date of FDA approval. Only one patent applicable to an approved product is eligible for the extension, and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. Additionally, the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The United States Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA. In the future, if our product candidates receive approval by the FDA, we expect to apply for patent term extensions on one issued patent covering each of those products, depending upon the length of the clinical studies for each product and other factors. There can be no assurance that patents will issue from our current or future pending patent applications, or that we will benefit from any patent term extension or favorable adjustments to the terms of any patents we may own or in-license in the future. In addition, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. The patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

RLY-4008

As of February 28, 2021, we co-owned with D. E. Shaw Research pending PCT, Argentine, and Taiwanese applications which relate to our FGFR2 inhibitors. Any U.S. or foreign patent that may issue from these patent applications would be scheduled to expire in 2040, excluding any additional term for patent term adjustment or patent term extension, if applicable. As of February 28, 2021, we wholly-owned a pending U.S. provisional patent application relating to RLY-4008 composition of matter, methods of treatment, solid forms and methods of manufacture. Any U.S. or foreign patent that may issue from a non-provisional patent application claiming priority

to this application would be scheduled to expire in 2041, excluding any additional term for patent term adjustment or patent term extension, if applicable.

Mutant-PI3Kα Inhibitor Program

As of February 28, 2021, we co-owned with D.E. Shaw Research pending U.S. provisional patent applications that cover our PI3K program, which are directed to the composition of matter for the drug candidates of the program, analogs thereof, as well as methods of making and using these compounds. Any U.S. or foreign patent that may issue from a non-provisional patent application claiming priority to this applications would be scheduled to expire in 2041, excluding any additional term for patent term adjustment or patent term extension, if applicable.

RLY-1971

We wholly own a U.S. patent which relates to RLY-1971 composition of matter, which is scheduled to expire in 2039, excluding any additional term for patent term adjustment or patent term extension, if applicable. As of February 28, 2021, we co-owned with D. E. Shaw Research pending United States and foreign applications, which relate to SHP2 inhibitor compositions of matter and methods of treatment. Any U.S. or foreign patent that may issue from these patent applications would be scheduled to expire in 2039, excluding any additional term for patent term adjustment or patent term extension, if applicable. As of February 28, 2021, we wholly-owned pending U.S., PCT, Argentine and Taiwanese patent applications which relate to RLY-1971, solid forms and methods of manufacture. Any U.S. or foreign patent that may issue from a non-provisional patent application claiming priority to these patent applications would be scheduled to expire in 2040, excluding any additional term for patent term adjustment or patent term extension, if applicable.

Pursuant to the Genentech Agreement, we have granted an exclusive, worldwide, royalty-bearing license to Genentech, with the right to sublicense, develop and commercialize RLY-1971 and any other SHP2 inhibitors developed under the Genentech Agreement. Genentech has the first right, but not the obligation, to file, prosecute and maintain any patents licensed to it, as well as to enforce infringement of or defend claims against such patents that relate to RLY-1971 or other SHP2 inhibitors. See "—Our Collaborations—License Agreements and Strategic Collaborations—Genentech Collaboration and License Agreement" for more information on the Genentech Agreement.

Prosecution of the PCT patent application covering our FGFR2 inhibitors and the provisional patent application covering our PI3K program has not commenced, and will not commence unless and until they are timely converted into U.S. non-provisional or national stage applications. Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO or other foreign jurisdiction are often significantly narrowed by the time they issue, if they issue at all. Any U.S. or foreign patent issuing from these provisional, PCT, or foreign patent applications (assuming they are timely converted into non-provisional applications, and such non-provisional applications are granted as issued patents) would be scheduled to expire in 2040 or 2041 (for our FGFR2 applications) or 2041 (for our PI3K application), excluding any additional term for patent term adjustment or patent term extension, and assuming national phase entries are timely made based upon the pending PCT application, and payment of all applicable maintenance or annuity fees. Any of our pending PCT patent applications are not eligible to become issued patents until, among other things, we file national stage patent applications within 30 months in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent applications and any patent protection on the inventions disclosed in such PCT patent applications. Our provisional patent applications may never result in issued patents and are not eligible to become issued patents until, among other things, we file a non-provisional patent application and/or PCT patent application within 12 months of filing the related provisional patent application. If we do not timely file non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional and national stage patent applications relating to our provisional and PCT patent applications, we cannot predict whether any of our current or future patent applications for any of our product candidates or technology, will issue as patents. If we do not successfully obtain patent protection, or, even if we do obtain patent protection, if the scope of the patent protection we, Genentech, or our potential licensors, obtain with respect to any of our product candidates or technology is not sufficiently broad, we will be unable to prevent others

from using our technology or from developing or commercializing technology and products similar or identical to ours or other competing products and technologies.

In addition to patent applications, we rely on unpatented trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and confidential know-how are difficult to protect. In particular, we anticipate that with respect to the building of our compound library, our trade secrets and know-how will over time be disseminated within the industry through independent development and public presentations describing the methodology. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors and non-competition, non-solicitation, confidentiality and invention assignment agreements with our employees and consultants. We have also executed agreements requiring assignment of inventions with selected consultants, scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee that we will have executed such agreements with all applicable employees and contractors, or that these agreements will afford us adequate protection of our intellectual property and proprietary information rights. In addition, our trade secrets and/or confidential know-how may become known or be independently developed by a third party or misused by any collaborator to whom we disclose such information. These agreements may also be breached, and we may not have an adequate remedy for any such breach. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. For more information regarding the risks related to our intellectual property, please see “Risk Factors—Risks Related to our Intellectual Property.”

Commercialization

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization in the United States to sell our products. We believe that such an organization will be able to address the community of oncologists who are the key specialists in treating the patient populations for which our product candidates are being developed. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties for any of our product candidates that obtain marketing approval.

We also plan to build a marketing and sales management organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine.

Manufacturing

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates undergoing preclinical testing, as well as for clinical testing and commercial manufacture if our product candidates receive marketing approval.

All of our drug candidates are small molecules and are manufactured in synthetic processes from available starting materials. The chemistry appears amenable to scale-up and does not currently require unusual equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

We generally expect to rely on third parties for the manufacture of companion diagnostics for our products, which are assays or tests to identify an appropriate patient population. Depending on the technology solutions we choose, we may rely on multiple third parties to manufacture and sell a single test.

Governmental 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, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs. We, along with our vendors, contract research organizations and contract manufacturers, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, where we are initially focusing our drug development, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, as amended, its implementing regulations and other laws. If we fail to comply with applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other legal requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject to administrative or judicial sanctions or other legal consequences. These sanctions or consequences could include, among other things, the FDA's refusal to approve pending applications, issuance of clinical holds for ongoing studies, suspension or revocation of approved applications, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before our product candidates are approved as drugs for therapeutic indications and may be marketed in the United States generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice, or GLP, requirements;
- completion of the manufacture, under current Good Manufacturing Practices, or cGMP, conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin;
- approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of a New Drug Application, or NDA;
- a determination by the FDA within 60 days of its receipt of an NDA, to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potentially, satisfactory completion of FDA audit of the clinical trial sites that generated the data in support of the NDA;
- payment of user fees for FDA review of the NDA; and

- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

Preclinical studies and clinical trials for drugs

Before testing any drug in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulation, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a full or partial clinical hold. FDA must notify the sponsor of the grounds for the hold and any identified deficiencies must be resolved before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND. A clinical hold can also be imposed once a trial has already begun, thereby halting the trial until the deficiencies articulated by FDA are corrected.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, who generally are physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable compared to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about clinical trials, including results for clinical trials other than Phase 1 investigations, must be submitted within specific timeframes for publication on www.ClinicalTrials.gov, a clinical trials database maintained by the National Institutes of Health.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, FDA will nevertheless accept the results of the study in support of an NDA if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate therapeutic indications to support NDAs for marketing approval are typically conducted in three sequential phases, which may overlap.

- *Phase 1*—Phase 1 clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, excretion the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- *Phase 2*—Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the drug's potential efficacy, to determine the optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.

- *Phase 3*—Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and physician labeling.

In August 2018, the FDA released a draft guidance entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics," which outlines how drug developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology drug development (i.e., the first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to drug development and reduce development costs and time.

Post-approval trials, sometimes referred to as Phase 4 clinical trials or post-marketing studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of NDA approval.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human volunteers and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

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

U.S. marketing approval for drugs

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA package requesting approval to market the product for one or more indications. An NDA is a request for approval to market a new drug for one or more specified indications and must contain proof of the drug's safety and efficacy for the requested indications. The marketing application is required to include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use 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 efficacy of the investigational product to the satisfaction of the FDA. FDA must approve an NDA before a drug may be marketed in the United States.

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective for the indications sought and whether the facility in which it is

manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets ten months, from the filing date, in which to complete its initial review of a new molecular entity NDA and respond to the applicant, and six months from the filing date of a new molecular entity NDA for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each NDA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy, or REMS, if it believes that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh its risks. A REMS can include use of risk evaluation and mitigation strategies like medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk-minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA 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 are adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, depending on the specific risk(s) to be addressed it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Orphan drug designation and exclusivity

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 if it

affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the product available in the United States for the disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan products are eligible for certain incentives, including tax credits for qualified clinical testing and waiver of application fees.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity during which the FDA may not approve any other applications to market the same therapeutic agent for the same indication, except in limited circumstances, such as a subsequent product's showing of clinical superiority over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. Competitors, however, may receive approval of different therapeutic agents for the indication for which the orphan product has exclusivity or obtain approval for the same therapeutic agent for a different indication than that for which the orphan product has exclusivity. Orphan product exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for the same therapeutic agent for the same indication before we do, unless we are able to demonstrate that our product is clinically superior. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. Further, 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 the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited development and review programs for drugs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval, and the purpose of these programs is to either expedite the development or review of important new drugs to get them to patients more quickly than standard FDA review timelines typically permit.

A new drug is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. Rolling review means that the agency may review portions of the marketing application before the sponsor submits the complete application. In addition, a new drug may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient drug development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and Accelerated Approval. A product is eligible for Priority Review, once an NDA or BLA is submitted, if the drug that is the subject of the marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the FDA's goal date to take action on the marketing application is six months compared to ten months for a standard review. Products are eligible for Accelerated Approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, which 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.

Accelerated Approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. The FDA may withdraw approval of a drug or an indication approved under Accelerated Approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, as a condition for Accelerated Approval, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period. After the 120-day period has passed, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

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. Furthermore, 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, though they may expedite the development or review process.

Pediatric information and pediatric exclusivity

Under the Pediatric Research Equity Act, or PREA, as amended, certain NDAs and NDA supplements must contain data that can be used 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. The FD&C Act requires that a sponsor who 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, or PSP, 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 the Phase 3 or Phase 2/3 study. The initial PSP 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 PSP. A sponsor can submit amendments to an agreed-upon initial PSP 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 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.

U.S. post-approval requirements for drugs

Drugs manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. 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, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and

monitor the product's safety and effectiveness after commercialization. In addition, drug manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements. Failure to comply with statutory and regulatory requirements may subject a manufacturer to legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual prescription drug product program user fee.

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, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

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

Regulation of companion diagnostics

Companion diagnostics identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics are regulated as medical devices by the FDA. In the United States, the FD&C Act, and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption or FDA exercise of enforcement discretion applies, diagnostic tests generally require marketing clearance or approval from the FDA prior to commercialization. The two primary types of FDA marketing authorization applicable to a medical device are clearance of a premarket notification, or 510(k), and approval of a premarket approval application, or PMA.

To obtain 510(k) clearance for a medical device, or for certain modifications to devices that have received 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a pre-amendment device that was in commercial distribution before May 28, 1976, or a predicate device, for which the FDA has not yet called for the submission of a PMA. In making a determination that the device is substantially equivalent to a predicate device, the FDA compares the proposed device to the predicate device and assesses whether the subject device is comparable to the predicate device with respect to intended use, technology, design and other features which could affect safety and effectiveness. If the FDA determines that the subject device is substantially equivalent to the predicate device, the subject device may be cleared for marketing. The 510(k) premarket notification pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer.

A PMA must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the quality system regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. The FDA's review of an initial PMA is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny the approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

On July 31, 2014, the FDA issued a final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the guidance document, for novel therapeutic products that depend on the use of a diagnostic test and where the diagnostic device could be essential for the safe and effective use of the corresponding therapeutic product, the companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic, although the FDA recognizes that there may be cases when contemporaneous development may not be possible. However, in cases where a drug cannot be used safely or effectively without the companion diagnostic, the FDA's guidance indicates it will generally not approve the drug without the approval or clearance of the diagnostic device. The FDA also issued a draft guidance in July 2016 setting forth the principles for co-development of an in vitro companion diagnostic device with a therapeutic product. The draft guidance describes principles to guide the development and contemporaneous marketing authorization for the therapeutic product and its corresponding in vitro companion diagnostic.

Once cleared or approved, the companion diagnostic device must adhere to post-marketing requirements including the requirements of the FDA's QSR, adverse event reporting, recalls and corrections along with product marketing requirements and limitations. Like drug makers, companion diagnostic makers are subject to unannounced FDA inspections at any time during which the FDA will conduct an audit of the product(s) and the company's facilities for compliance with its authorities.

Other regulatory matters

Manufacturing, sales, promotion and other activities of product candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Other healthcare laws

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti-kickback,

false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

- The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; a person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim that includes 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. On November 20, 2020, the Office of Inspector General, or OIG, finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. These rules (with exceptions) became effective January 19, 2021. We continue to evaluate what effect, if any, these rules will have on our business.
- The federal civil and criminal false claims laws, including the civil False Claims Act, or FCA, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.
- The federal civil monetary penalties laws impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary, if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies.
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates in some cases, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions.
- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and

medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. In addition, many states also require reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners.

- Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.
- Analogous state and foreign laws and regulations may be broader in scope than the provisions described above and may apply regardless of payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and relevant federal government compliance guidance; require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers; restrict marketing practices or require disclosure of marketing expenditures and pricing information. State and foreign laws may govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts.

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. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from its business.

Insurance coverage and reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit

coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, which will require additional expenditure above and beyond the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Current and future healthcare reform legislation

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the United States Congress enacted the Affordable Care Act, which, among other things, includes changes to the coverage and payment for products under government health care programs. The Affordable Care Act includes provisions of importance to our potential product candidates that:

- created an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide point-of-sale-discounts off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. For example, various portions of the Affordable Care Act are currently facing legal and constitutional challenges in the Fifth Circuit Court of Appeals and the United States Supreme Court. Additionally, the previous administration issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the Affordable Care Act. It is unclear whether the Affordable Care Act will be overturned, repealed, replaced, or further amended. We cannot predict what effect further changes to the Affordable Care Act would have on our business, especially given the new administration.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020, and subsequent legislation, suspended these reductions from May 1, 2020 through March 31, 2021. Proposed legislation, if passed, would extend this suspension until the end of the COVID-19 pandemic. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, including bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. For example, at the federal level, the previous administration’s budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the previous administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the previous administration also released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS’s policy change that was effective January 1, 2019. It is unclear whether the current administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021. Although a number of these and other measures may require additional authorization to become effective, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the FYs 2019 and 2018 reimbursement formula on specified covered outpatient drugs, or SCODs. The court ruled this change was not an “adjustment” which was within the Secretary’s discretion to make but was instead a fundamental change in the reimbursement calculation. However, most recently,

on July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court's decision and found that the changes were within the Secretary's authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), but was denied on October 16, 2020. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any.

Further, on July 24, 2020 and September 13, 2020, the previous administration issued several executive orders related to prescription drug pricing that sought to implement several of the previous administration's proposals. In response, the FDA released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. The Interim Final Rule has not been finalized and is subject to revision and challenge. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Implementation of the November 20, 2020 final Rule will be delayed until at least January 1, 2023. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs. Additionally, in the United States, the Medicare Modernization Act, or MMA, contains provisions that call for the promulgation of regulations that expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. Further, the MMA provides that these changes to U.S. importation laws will not take effect, unless and until the Secretary of the HHS certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the Secretary of the HHS made such certification to Congress, and on October 1, 2020, FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, states and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. Since the issuance of the final rule, several industry groups have filed federal lawsuits challenging multiple aspects of the final rule, and authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed upon. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Compliance with other federal and state laws or requirements; changing legal requirements

If any products that we may develop are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, labeling, packaging, distribution, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to which we may be subject.

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

The failure to comply with any of these laws or regulatory requirements may subject firms to legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, relabeling or repackaging, or refusal to allow a firm to enter into supply contracts, including government contracts. Any claim or action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Prohibitions or restrictions on marketing, sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling or packaging; (iii) the recall or discontinuation of our products; or (iv) additional recordkeeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other U.S. environmental, health and safety laws and regulations

We may be 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. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our 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 for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Government regulation of drugs outside of the United States

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization or identification of an alternate regulatory pathway, manufacturing, commercial sales and distribution of our products. For instance, in the United Kingdom and the European Economic Area, or the EEA (comprised of the 27 EU Member States plus Iceland, Liechtenstein and Norway), medicinal products must be authorized for marketing by using either the centralized authorization procedure or national authorization procedures.

- *Centralized procedure*—If pursuing marketing authorization of a product candidate for a therapeutic indication under the centralized procedure, following the opining of the EMA's Committee for Medicinal Products for Human Use, or, CHMP, the European Commission issues a single marketing authorization valid across the EEA. The centralized procedure is compulsory for human medicines derived from biotechnology processes or advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions, viral diseases, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned contains a new active substance not yet authorized in the EEA, is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the EEA. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding clock stops.
- *National authorization procedures*—There are also two other possible routes to authorize products for therapeutic indications in several countries, which are available for products that fall outside the scope of the centralized procedure:
    - *Decentralized procedure*—Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.

- *Mutual recognition procedure*—In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, additional marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned recognize the validity of the original, national marketing authorization.

In the EEA, new products for therapeutic indications that are authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or 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 marketing authorization 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 ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization 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.

The criteria for designating an "orphan medicinal product" in the EEA are similar in principle to those in the United States. In the EEA a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five 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 investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten-year orphan market exclusivity period, no marketing authorization application shall be accepted, and no marketing authorization shall be granted for a similar medicinal product for the same indication. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. The ten-year market exclusivity 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 orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization 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.

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

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU Member States govern the system for the approval of clinical trials in the European Union. Under this system, an applicant must obtain prior approval from the competent national authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an investigational medicinal product dossier (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the implementing national provisions of the individual EU Member States and further detailed in applicable guidance documents.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation) was adopted. It is expected that the new Clinical Trials Regulation (EU) No 536/2014 will apply following confirmation of full functionality of the Clinical Trials Information System (CTIS), the centralized European Union portal and database for clinical trials foreseen by the regulation, through an independent audit. The regulation becomes applicable six months after the European Commission publishes notice of this confirmation. The Clinical Trials Regulation will be directly applicable in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions

until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial. The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

Government regulation of data collection outside of the United States

In the event we conduct clinical trials in the European Union, we will be subject to additional privacy restrictions. The collection and use of personal health data in the European Economic Area, or EEA (being the European Union plus Norway, Iceland, and Liechtenstein), is governed by the General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018. The GDPR applies to the processing of personal data by any company established in the EEA and to companies established outside the EEA to the extent they process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR enhances data protection obligations for data controllers of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, mandatory data breach notification and "privacy by design" requirements, and creates direct obligations on service providers acting as processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the United States (which, while deemed a third country, has the benefit of the Privacy Shield regime for transatlantic data transfers). Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States and Norway, Iceland and Liechtenstein, which may deviate slightly from the GDPR, may result in fines of up to 4% of a company's global revenues for the preceding financial year, or €20,000,000, whichever is greater. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR will require significant time, resources and expense, and we may be required to put in place additional controls and processes ensuring compliance with the new data protection rules. There has been limited enforcement of the GDPR to date, particularly in biopharmaceutical development, so we face uncertainty as to the exact interpretation of the new requirements on any future trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law. Further, the United Kingdom's decision to leave the European Union, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the European Union.

There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the EU, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance are onerous and may adversely affect our business, financial condition, results of operations and prospects.

Should we utilize third party distributors, compliance with such foreign governmental regulations would generally be the responsibility of such distributors, who may be independent contractors over whom we have limited control.

Human Capital Resources

As of February 28, 2021, we had 159 full-time employees. Seventy-four of our employees have M.D. or Ph.D. degrees. Within our workforce, 114 employees are engaged in research and development and 45 are engaged in business development, finance, legal, and general management and administration. 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.

We believe that our people are among our greatest assets. Accordingly, we are committed to building a dedicated and passionate team. We focus on recruiting talent that is additive to our existing teams and leverage a diversity of perspectives. We regularly review our compensation practices and analyze the equity of our compensation decisions for all employees. We provide what we consider to be a competitive mix of long and short-term incentives including competitive salaries, incentive compensation, participation in our equity programs, healthcare and insurance benefits, and various innovative health and wellness programs.

We are committed to investing in the development of our employees and creating an environment where diverse perspectives and backgrounds are encouraged and supported. To empower our employees to continually develop and grow, we offer a wide range of learning and development opportunities and resources. These include formal leadership training, workshops, and access to specialized career coaching to foster continued growth. We also host regular company-wide sessions where our employees discuss ideas and feedback on corporate initiatives, share scientific breakthroughs and other corporate updates and recognize each other’s contributions and accomplishments. In addition, we regularly conduct an employee survey to gauge employee engagement and identify areas of focus.

We are also dedicated to providing an inclusive, collaborative and safe work environment for our employees. Our diversity and inclusion advisory group actively promotes engagement among our employees on a variety of topics related to diversity, equity and inclusion, including providing awareness workshops and supporting the growth of employee resource groups for under-represented populations as part of our efforts to create a more diverse and equitable workplace.

In response to the COVID-19 pandemic, we undertook several initiatives to ensure the health and safety of our workforce and continuity of our operations. We developed and implemented safety protocols at our facilities taking into consideration national and local public health guidelines and input from our employees. We rapidly redesigned our facilities and introduced company-sponsored regular onsite COVID-19 testing as well as provided access to testing for family and household members of employees. Throughout the pandemic, much of our workforce has worked remotely, wherever possible. We also implemented remote hiring and onboarding programs to facilitate significant hiring during 2020 in a remote work environment.

Corporate Information

We were incorporated under the laws of the State of Delaware on May 4, 2015 under the name Allostery, Inc. In December 2015, we changed our name to Relay Therapeutics, Inc. Our principal corporate office is located at 399 Binney Street, 2nd Floor, Cambridge, MA 02139, and our telephone number is (617) 370-8837. Our website address is www.relaytx.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K.

In July 2020, we completed our initial public offering, or IPO, pursuant to which we issued and sold 23,000,000 shares of common stock at a public offering price of $20.00 per share, resulting in net proceeds of $425 million, after deducting underwriting discounts and commissions and other offering expenses.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock

that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Available Information

Our website address is www.relaytx.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available through the "Media & Investors" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Our code of conduct, corporate governance guidelines and the charters of our Audit Committee, Research and Development Committee, Compensation Committee and Nominating and Corporate Governance Committee are available through the "Media & Investors" portion of our website.

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 consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. We believe the risks described below include risks that are material to us as well as other risks that may adversely affect our business, financial condition, results of operations 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.

Risks Related to Our Product Candidates

Risks Related to Clinical Development

We have never successfully completed any clinical trials, and we may be unable to do so for any product candidates we develop.

We have not yet demonstrated our ability to successfully complete any clinical trials, including large-scale, pivotal clinical trials, obtain regulatory 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 commercialization. We have two product candidates, RLY-1971 and RLY-4008, in first-in-human clinical development. We expect to be in IND-enabling studies for our RLY-PI3K1047 program by the end of 2021. We may not be able to file such IND or INDs for any of our other product candidates on the timelines we expect, if at all. For example, we may experience manufacturing delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that require us to suspend or terminate clinical trials. Commencing each of these clinical trials is subject to finalizing the trial design based on discussions with the FDA and other regulatory authorities. Any guidance we receive from the FDA or other regulatory authorities is subject to change. These regulatory authorities could change their position, including, on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or impose stricter approval conditions than we currently expect. Successful completion of our clinical trials is a prerequisite to submitting a new drug application, or NDA, to the FDA and a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, for each product candidate and, consequently, the ultimate approval and commercial marketing of each product candidate. Our RLY-1971 and RLY-4008 first-in-human clinical trials are ongoing, but we do not know whether any of our future clinical trials will begin on time or ever be completed on schedule, if at all.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Clinical product development involves a lengthy and expensive process, with an uncertain outcome.

It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials

can occur at any stage of testing. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Our preclinical studies and future clinical trials may not be successful.

From time to time, we may publish interim top-line or preliminary data from our clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

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

We may experience delays in completing our preclinical studies and initiating or completing clinical trials, and we may experience numerous unforeseen events during, or as a result of, any future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- 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;
- we may elect to, or regulators or IRBs or ethics committees may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination or clinical hold 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, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental 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 regulatory approval of our product candidates. Further, the FDA may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

Our product development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our future clinical trials will begin as planned, or whether any of our current or future clinical trials will need to be restructured or will be completed on schedule, if at all. Significant preclinical study or clinical trial delays, including those caused by the COVID-19 pandemic, also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. Any delays in our preclinical or future clinical development programs may harm our business, financial condition and prospects significantly.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

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 as required by the FDA or similar regulatory authorities outside the United States. In particular, because we will be deploying our drug discovery platform across a broad target space, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Furthermore, our ability to enroll patients may be significantly delayed by the evolving COVID-19 pandemic and we do not know the extent and scope of such delays at this point.

In addition to the competitive trial environment, the eligibility criteria of our planned clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure to assure their cancer is either severe enough or not too advanced to include them in a study. Additionally, the process of finding patients may prove costly. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidates under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed.

We may also engage third parties to develop companion diagnostics for use in our clinical trials, but such third parties may not be successful in developing such companion diagnostics, furthering the difficulty in identifying patients with the targeted genetic mutations for our clinical trials. Further, if we are required to develop companion diagnostics and are unable to include patients with the targeted genetic mutations, this could compromise our ability to seek participation in the FDA's expedited review and development programs, including Breakthrough Therapy Designation and Fast Track Designation, or otherwise to seek to accelerate clinical development and regulatory timelines. The FDA has indicated that if we continue RLY-4008 in a specific biomarker-defined population, a companion diagnostic device will be required to ensure its safe and effective use.

Patient enrollment may be affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the clinical trial in question;
- the availability of an appropriate genomic screening test;
- the perceived risks and benefits of the product candidate under study;

- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; and
- factors we may not be able to control, such as current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e.g., outbreak of COVID-19).

Positive results from early preclinical studies of our product candidates are not necessarily predictive of the results of later preclinical studies and any future clinical trials of our product candidates. If we cannot replicate the positive results from our earlier preclinical studies of our product candidates in our later preclinical studies and future clinical trials, we may be unable to successfully develop, obtain regulatory for and commercialize our product candidates.

Any positive results from our preclinical studies of our product candidates may not necessarily be predictive of the results from required later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or any future clinical trials of our product candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or EMA approval.

Our current or future clinical trials or those of our future collaborators may reveal significant adverse events not seen in our preclinical or nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. 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. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials also may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and 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.

We may develop future product candidates, in combination with one or more cancer therapies. The uncertainty resulting from the use of our product candidates in combination with other cancer therapies may make it difficult to accurately predict side effects in future clinical trials.

As is the case with many treatments for cancer and rare diseases, it is likely that there may be side effects associated with the use of our product candidates. If significant adverse events or other side effects are observed in any of our

current or future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, the FDA or other applicable regulatory authorities, or an IRB may suspend or terminate clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Although we intend to explore other therapeutic opportunities, in addition to the product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. For example, pursuant to the DESRES Agreement, we collaborate with D. E. Shaw Research to develop various protein models and make predictions as to how molecules might move, with subsequent validation efforts in our and our CROs' labs. There can be no assurance that we will find potential additional targets using this approach, that any such targets will be tractable, or that such clinical validations will be successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective products; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

We intend to develop our current product candidates and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.

We intend to develop our current product candidates, and may develop future product candidates, for use in combination with one or more currently approved cancer therapies. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to bear the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for

indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our current product candidates or any other 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 foreign regulatory authorities. We will not be able to market and sell our SHP2 program, our FGFR2 program, or our PI3K program or any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. Pursuant to the Genentech Agreement as further described above, Genentech will assume the development of RLY-1971, including developing RLY-1971 in combination with Genentech's KRAS ^{G12C} program.

If the FDA or similar foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with our current product candidates or any product candidate we develop, we may be unable to obtain approval of or market our SHP2 program, our FGFR2 program, or our PI3K program or any product candidate we develop.

Our product candidates utilize a novel mechanism of action and novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.

Our product candidates utilize novel mechanisms of action and novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects. Our Dynamo platform uses advanced computational models in tight integration with our medicinal chemistry, structural biology, enzymology and biophysics capabilities to predict and design the compounds that will achieve the most desirable characteristics, including potency, selectivity, bioavailability, and drug-like properties. A disruption in any of these capabilities may have significant adverse effects in our abilities to expand our Dynamo platform, and we cannot predict whether we will continue to have access to these capabilities in the future to support our Dynamo platform. In addition, there can be no assurance that we will be able to rapidly identify, design and synthesize the necessary compounds or that these or other problems related to the development of this novel mechanism will not arise in the future, which may cause significant delays, or we raise problems we may not be able to resolve.

Regulatory approval of novel product candidates such as ours can be more expensive, riskier and take longer than for other, more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to our and regulatory agencies' lack of experience with them. The novelty of our mechanism of action may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. The novel mechanism of action also means that fewer people are trained in or experienced with product candidates of this type, which may make it more difficult to find, hire and retain personnel for research, development and manufacturing positions. Because our inhibitors utilize a novel mechanism of action that has not been the subject of extensive study compared to more well-known product candidates, there is also an increased risk that we may discover previously unknown or unanticipated adverse effects during our preclinical studies and clinical trials. Any such events could adversely impact our business prospects, financial condition and results of operations.

We may in the future conduct clinical trials for our product candidates outside the United States, and the FDA and similar foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct additional clinical trials outside the United States, including in Australia, Europe, Asia or other foreign jurisdictions. The acceptance of trial data from clinical trials conducted outside the United States by the FDA may be subject to certain conditions. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials were performed by clinical investigators of recognized competence and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an

on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Risks Related to Obtaining Regulatory Approvals

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

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates, we must obtain marketing approval. Currently, all of our product candidates are in development, and we have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. It is possible that our product candidates, including any product candidates we may seek to develop in the future, will never obtain regulatory approval. We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. In addition, regulatory authorities may find fault with our manufacturing process or facilities or that of third-party contract manufacturers. We may also face greater than expected difficulty in manufacturing our product candidates.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive and often takes many years. If the FDA or a comparable foreign regulatory authority requires that we perform additional preclinical or clinical trials, approval, if obtained at all, may be delayed. The length of such a delay varies substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted NDA, 510(k), premarket approval application, or PMA, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

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

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

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

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

Risks Related to Commercialization

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

We are currently evaluating the safety and tolerability of RLY-1971 in a Phase 1 dose escalation study in patients with advanced or metastatic solid tumors and pursuant to the Genentech Agreement entered into in December 2020, future development for RLY-1971, including the potential to conduct multiple combination studies, will be governed by a joint development team between us and Genentech. We estimate there are approximately 55,000 late-line patients annually in the United States with advanced lung cancer who might benefit from a combination of RLY-1971 with another targeted inhibitor. In the future, if RLY-1971 advances to earlier lines of combination treatment for lung cancer, we believe it could be applied in the treatment of approximately 90,000 patients annually in the United States. The subset of patients with KRAS ^{G12C} mutations in lung cancer that could potentially benefit from the combination of RLY-1971 with GDC-6036 is approximately 15,000-25,000 annually in the United States. We are also evaluating the safety and tolerability of RLY-4008, our inhibitor of FGFR2 in patients with advanced solid tumors having oncogenic FGFR2 alterations, in a first-in-human trial initiated in September 2020. We believe FGFR2-mediated cancers affect approximately 8,000 late-line patients annually in the United States, of which fusions represent approximately 2,700, amplifications 1,600, and mutations 3,800. In the future, if RLY-4008 advances to earlier lines of treatment, it could potentially address approximately 20,000 patients annually in the United States.

We expect to be in IND-enabling studies for our RLY-PI3K1047 program by the end of 2021. We believe PI3Kα H1047X mutant cancers affect approximately 10,000 late-line patients annually in the United States. In the future, if RLY-PI3K1047 advances to earlier lines of treatment, it could potentially address approximately 50,000 patients annually in the United States. Two additional mutations of interest for our PI3Kα franchise are E542X and E545X. We estimate there are approximately 15,000 late-line and 60,000 total patients annually in the United States who might benefit from a PI3Kα targeted inhibitor that targets the mutations at E542 and E545. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the

potential to benefit from treatment with RLY-1971, RLY-4008, or our RLY-PI3K1047 program or other product candidates, are based on estimates.

The total addressable market opportunity will ultimately depend upon, among other things, the diagnosis criteria included in the final label, if our product candidates are approved for sale for these indications, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients with cancers and solid tumors may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, which may prove to be the wrong choice and may adversely affect our business.

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

The development and commercialization of new products in the biopharmaceutical and related industries is highly competitive. We compete in the segments of the pharmaceutical, biotechnology, and other related markets that address computationally focused structure-based drug design in cancer and genetic diseases. There are other companies focusing on structure-based drug design to develop therapies in the fields of cancer and other diseases. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

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 from segments of the pharmaceutical, biotechnology and other related markets that pursue precision medicines. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. We believe principal competitive factors to our business include, among other things, the accuracy of our computations and predictions, ability to integrate experimental and computational capabilities, ability to successfully transition research programs into clinical development, ability to raise capital, and the scalability of the platform, pipeline, and business.

Many of the companies that we compete against or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, we cannot predict whether our current competitive advantages, such as our ability to leverage our Dynamo platform and our relationship with D. E. Shaw Research, will remain in place in the future. If these or other barriers to entry do not remain in place, other companies may be able to more directly or effectively compete with us.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy,

safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for any of our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration 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. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Factors payors consider in determining reimbursement are based on whether the product is (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no

assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Risks Related to Our Reliance on Third Parties

Under the DESRES Agreement, we collaborate with D. E. Shaw Research to rapidly develop various protein models, a process that depends on D. E. Shaw Research's use of their proprietary supercomputer, Anton 2. A termination of the DESRES Agreement could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Under the DESRES Agreement, we collaborate with D. E. Shaw Research to develop various protein models to make predictions as to how molecules might move in connection with identifying potential new biological targets and prospective drug compounds. There can be no assurance these protein models, or the technology used by D. E. Shaw Research to develop them (including the Anton 2 supercomputer), will provide reliable data or target information, or that the findings from these activities and our subsequent validation efforts will translate into the ability to develop therapeutically effective compounds. Our collaboration with D. E. Shaw Research is our key computational collaboration, and there can be no assurance that this collaboration will continue past the current term of the DESRES Agreement, on favorable terms or at all, or that at any time while the collaboration is in effect D. E. Shaw Research will provide a level of service that benefits our programs in a meaningfully positive manner. While we also have other computational collaborations, mostly focused on developing machine learning models, such collaborations do not provide a substitute for the technology made available through our collaboration with D. E. Shaw Research. The termination of the DESRES Agreement or any reduction in our collaboration with D. E. Shaw Research would require us to rely more heavily on these other collaborations and our own internal resources, and may delay or impair our development efforts.

Furthermore, while the termination of the DESRES Agreement would not directly impact the development of our lead product candidates, we cannot predict the effects such termination could have on our preclinical studies and development efforts and our ability to discover and develop additional product candidates. In particular, the technologies accessed through D. E. Shaw Research, including the Anton 2 supercomputer, are important aspects of our Dynamo platform, and we do not currently have access to another source of computational power comparable to that provided by the Anton 2 supercomputer. Currently, not only is our collaboration with D. E. Shaw Research for a limited time period, but it is also limited in the current collaboration year to collaboration across a total of eleven target proteins (with such number subject to increases or decreases from year to year, with any increase in such number of targets in each collaboration year capped at four more than the highest number of such targets in the previous year, and with the number of targets capped at twenty, subject to some limitations), which could restrict our ability to broaden our platform across a larger number of targets and programs.

Under the DESRES Agreement, D. E. Shaw Research controls the rights to its technology, we control the rights to certain compounds, and we jointly own with D. E. Shaw Research any other work product created by D. E. Shaw Research and us. Any work product we jointly own with D. E. Shaw Research and any other information that we or D. E. Shaw Research share is subject to a non-exclusive cross-license between us and D. E. Shaw Research, subject to certain exceptions. In some instances, D. E. Shaw Research is required to assign to us some of the work product created by D. E. Shaw Research. Disputes may arise between us and D. E. Shaw Research, as well as any future potential collaborators, regarding intellectual property subject to the DESRES Agreement. If disputes over intellectual property that we co-own or we own individually prevent or impair our ability to maintain our current collaboration arrangements on acceptable terms, or undermine our ability to successfully control the intellectual property necessary to protect our product candidates, we may be unable to successfully develop and commercialize the affected product candidates. Uncertainties or disagreements around our rights under any such intellectual property may undermine our ability to partner our programs with third parties.

In addition, the DESRES Agreement is complex and certain provisions may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could be adverse to us, for example by narrowing what we believe to be the scope of our rights to certain intellectual property, or increasing

what we believe to be our financial or other obligations under the DESRES Agreement, and any such outcome could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we co-own, as we are for intellectual property that we own, which are described below. If we or D. E. Shaw Research fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

Moreover, we are subject to certain payment obligations under the DESRES Agreement, including payments to D. E. Shaw Research in connection with certain transactions, including our collaboration with Genentech pursuant to the Genentech Agreement. These payment obligations may decrease the value to us of certain transactional opportunities or otherwise burden our ability to enter into such transactions.

We rely on third parties to conduct our ongoing clinical trials of RLY-1971 and RLY-4008 and expect to rely on third parties to conduct future clinical trials, as well as investigator-sponsored clinical trials of 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 regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely and expect to continue to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support clinical trials for our product candidates, including our first-in-human clinical trials of RLY-1971 and RLY-4008, currently enrolling patients. We may also rely on academic and private non-academic institutions to conduct and sponsor clinical trials relating to our product candidates. We will not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

We rely and expect to continue to rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. 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 CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We, our principal investigators and our CROs are required to comply with regulations, including Good Clinical Practices, or GCPs, 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 Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we, our principal investigators or our CROs fail to comply with applicable GCPs, 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. We cannot assure you that, upon inspection, the FDA will

determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with product candidates produced under current Good Manufacturing Practice, or cGMP, regulations. Our failure or the failure of our principal investigators or CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we designed our first-in-human clinical trials of RLY-1971 and RLY-4008 and intend to design the future clinical trials for the product candidates that we develop, we expect that CROs will conduct all of our clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct future clinical trials also results 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 outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- 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 principal investigators or CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development program materially and irreversibly harmed. If we are unable to rely on clinical data collected by our principal investigators or CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party principal investigators or CROs terminate, we may not be able to enter into arrangements with alternative CROs. If principal investigators or CROs 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 is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such principal investigators or CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We contract with third parties for the manufacture of our product candidates for preclinical development, clinical testing, and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical development and clinical testing, as well as for the commercial manufacture of our products if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used by our contract manufacturers to manufacture our product candidates must be inspected by the FDA pursuant to pre-approval inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to pass regulatory inspections and/or maintain regulatory compliance for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it finds deficiencies or withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

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

- 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 nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates and any products that we may develop may compete with other product candidates and approved products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We are also unable to predict how the COVID-19 pandemic may affect our third-party manufacturers, including any potential disruptions to our global supply chain. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers or manufacture the materials ourselves, for which we may not have the capabilities or resources. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original contract manufacturing organization, or CMO, and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. Changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. We may incur added costs and delays in identifying and qualifying any such replacement. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates.

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

The third parties upon whom we rely for the supply of the active pharmaceutical ingredient used in our product candidates are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

The active pharmaceutical ingredients, or API, used in our product candidates are supplied to us from single-source suppliers. Our ability to successfully develop our product candidates, and to ultimately supply our commercial products in quantities sufficient to meet the market demand, depends in part on our ability to obtain the API for these products in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. We do not currently have arrangements in place for a redundant or second-source supply of any such API in the event any of our current suppliers of such API cease their operations for any reason. We are also unable to predict how changing global economic conditions or potential global health concerns such as the COVID-19 pandemic will affect our third-party suppliers and manufacturers. Any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition.

For all of our product candidates, we intend to identify and qualify additional manufacturers to provide such API prior to submission of an NDA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API used in our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory inspection or approval, which could result in further delay. While we seek to maintain adequate inventory of the API used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

We may enter into collaborations with third parties for the research, development, manufacture and commercialization of one or more of our programs or product candidates. If these collaborations are not successful, our business could be adversely affected.

We may enter into collaborations with third parties for one or more of our programs or product candidates. For example, in December 2020, we entered into the Genentech Agreement, a global collaboration and license agreement with Genentech to develop and commercialize RLY-1971. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that any future collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them.

Any collaborations we enter into, including our collaboration with Genentech, may pose several risks, including the following:

- Collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- Collaborators may not perform their obligations as expected;
- The clinical trials conducted as part of these collaborations may not be successful;
- Collaborators may not pursue development and/or commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization

programs based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;

- Collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- We may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates;
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- Product candidates developed in collaboration with us may be viewed by any collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- A collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;
- Disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any programs or product candidates, may cause delays or termination of the research, development, manufacture or commercialization of such programs or product candidates, may lead to additional responsibilities for us with respect to such programs or product candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- Collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation. For example, Genentech has the first right to enforce or defend certain of our intellectual property rights under our collaboration, and although we may have the right to assume the enforcement and defense of such intellectual property rights if Genentech does not, our ability to do so may be compromised by Genentech's actions;
- Disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- Collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- Collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. For example, Genentech may terminate its collaboration with us for convenience after a specified notice period.

If our collaborations do not result in the successful development and commercialization of products, or if one of any future collaborators terminates its agreement with us, we may not receive any milestone or royalty payments under the collaboration. If we do not receive the payments we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop our product candidates.

In addition, if any collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation among the business and financial communities could be adversely affected.

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

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration 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 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. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional 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.

Risks Related to Our Financial Position and Ability to Raise Additional Capital

Risks Related to Our Operating History

We are a biopharmaceutical company with a limited operating history.

We are a biopharmaceutical company with a limited operating history and have incurred net losses in each year since our inception. Our net losses were $52.4 million and $75.3 million for the years ended December 31, 2020 and 2019, respectively. We had an accumulated deficit of $404.2 million as of December 31, 2020. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We commenced operations in May 2015. Since inception, we have focused substantially all of our efforts and financial resources on developing our drug discovery platform and initial product candidates. We have no products approved for commercial sale and therefore have never generated any revenue from product sales, and we do not expect to in the foreseeable future. We have not obtained regulatory approvals for any of our product candidates and there is no assurance that we will obtain approvals in the future. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital.

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect our research and development expenses to significantly increase in connection with the commencement and continuation of clinical trials of our product candidates. In addition, if we obtain marketing approval for our product candidates, we will incur significant sales, marketing and outsourced-manufacturing expenses. We will also continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

The amount of our future losses is uncertain and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of 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 partners;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- the changing and volatile U.S. and global economic environments, including as a result of the COVID-19 pandemic; and
- future accounting pronouncements or changes in our accounting policies.

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. 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 guidance we may provide.

We have no products approved for commercial sale and have not generated any revenue from product sales

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our product sales and we do not expect to generate any revenue from the sale of products in the near future. We do not expect to generate significant revenue unless and until we obtain marketing approval of, and begin to sell one or more of our product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete preclinical studies;
- successfully enroll subjects in, and complete, clinical trials;
- have our IND applications go into effect for our planned clinical trials or future clinical trials;
- receive regulatory approvals from applicable regulatory authorities;
- initiate and successfully complete all safety studies required to obtain U.S. and foreign marketing approval for our product candidates;
- establish commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- launch commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- obtain and maintain acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively compete with other therapies;
- obtain and maintain healthcare coverage and adequate reimbursement;
- enforce and defend intellectual property rights and claims;
- take temporary precautionary measures to help minimize the risk of COVID-19 to our employees; and
- maintain a continued acceptable safety profile of the product candidates following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Risks Related to Raising Additional Capital

We will need to raise substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate some of our product development programs or commercialization efforts.

The development of pharmaceutical products is capital-intensive. We initiated a Phase 1 clinical trial of RLY-1971 in patients with advanced solid tumors and a first-in-human clinical trial of RLY-4008 enriched for patients with advanced solid tumors having oncogenic FGFR2 alterations. We are currently advancing most of our product candidates, including RLY-PI3K1047, through preclinical development. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, depending on the status of regulatory approval or, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our product candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, we are incurring additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate certain of our research and development programs or future commercialization efforts.

We expect that our existing cash and cash equivalents and investments will be sufficient to fund our operations through at least the next 12 months. Our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- the impact of any business interruptions to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers, or other vendors, resulting from the COVID-19 pandemic or similar public health crisis;
- the scope, progress, results and costs of our current and future clinical trials of RLY-4008 and additional preclinical research of our RLY-PI3K1047 program;
- the scope, progress, results and costs of drug discovery, preclinical research and clinical trials for our other product candidates;
- the number of future product candidates that we pursue and their development requirements;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the success of any existing or future collaborations that we may enter into with third parties;
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates, such as our collaboration with Genentech;
- the achievement of milestones or occurrence of other developments that trigger payments under any existing or future collaboration agreements, if any;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under any existing or future collaboration agreements, if any;
- the costs and timing of future commercialization activities, including drug sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval, to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of any collaborator that we may have at such time;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and our research and development activities; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical development testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Disruptions in the financial markets may make equity and debt financing more difficult to obtain, and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on

our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted, and the terms of those securities may include liquidation or other preferences that materially adversely affect your rights as a common stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to COVID-19 and the Global Economy

A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. The current COVID-19 pandemic has spread to most countries across the world, including all 50 states within the United States, including specifically Cambridge, Massachusetts where our primary office and laboratory space is located. The coronavirus pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which the coronavirus impacts our operations or those of our third-party partners, including our preclinical studies or clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. The continued spread of COVID-19 globally could adversely impact our preclinical or clinical trial operations in the United States, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. For example, similar to other biopharmaceutical companies, we may experience delays in initiating IND-enabling studies, protocol deviations, enrolling our clinical trials, or dosing of patients in our clinical trials as well as in activating new trial sites. COVID-19 may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. In addition, as a result of medical complications associated with SDC and mCPRC, the patient populations that our lead core and other core product candidates target may be particularly susceptible to COVID-19, which may make it more difficult for us to identify patients able to enroll in our current and future clinical trials and may impact the ability of enrolled patients to complete any such trials. Any negative impact COVID-19 has to patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Additionally, timely enrollment in planned clinical trials is dependent upon clinical trial sites which could be adversely affected by global health matters, such as pandemics. We plan to conduct clinical trials for our product candidates in geographies which are currently being affected by the coronavirus. Some factors from the coronavirus outbreak that will delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

- the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials;
- limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;
- the potential negative effect on the operations of our third-party manufacturers, suppliers or other collaboration partners;
- interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in our prospective clinical trials; and
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring many employees to work remotely, suspending all non-essential travel worldwide for our employees and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business. We cannot presently predict the scope and severity of the planned and potential shutdowns or disruptions of businesses and government agencies, such as the SEC or FDA.

These and other factors arising from the coronavirus could worsen in countries that are already afflicted with the coronavirus or could continue to spread to additional countries. Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of operation and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our product candidates.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, in 2008, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets and the current COVID-19 pandemic has caused significant volatility and uncertainty in U.S. and international markets. See "*—A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, or coronavirus, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.*" A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Risks Related to Our Intellectual Property

Risks Related to Protecting Our Intellectual Property

If we are unable to adequately protect our proprietary technology or obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our commercial success will depend in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our product candidates, and our core technologies, including our novel target discovery technology and our proprietary compound library and other know-how. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the United States and abroad related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. See "Business—Intellectual Property" for more information regarding the patent application status for our product candidates. Other than our U.S. patent relating to RLY-1971 composition of matter, we do not own or in-license any issued patents relating to our platform, our SHP2 program, our FGFR2 program, or our PI3K program.

Pursuant to the Genentech Agreement, we have granted an exclusive, worldwide, royalty-bearing license to Genentech, with the right to sublicense, develop and commercialize RLY-1971 and any other SHP2 inhibitors developed under the Genentech Agreement. Genentech has the first right, but not the obligation, to file, prosecute and maintain any patents licensed to it, as well as to enforce infringement of or defend claims against such patents that relate to RLY-1971 or other SHP2 inhibitors. See "Risks Related to Our Reliance on Third Parties—" We may enter into collaborations with third parties for the research, development, manufacture and commercialization of one or more of our programs or product candidates. If these collaborations are not successful, our business could be adversely affected." for a discussion of risks related to the protection of our intellectual property rights under our collaborations.

Most of the research and development for our programs has been performed under the DESRES Agreement. Under the DESRES Agreement, D. E. Shaw Research controls the rights to its technology (including its supercomputer and software, each of which are important aspects of our Dynamo platform), we control the rights to certain compounds, and we jointly own with D. E. Shaw Research any other work product created by D. E. Shaw Research and us. Subject to certain limits, we have the right to have the following work product assigned to us: the composition of matter, method of use, and method of manufacture of certain compounds directed to a Category 1 Target, as set forth in the DESRES Agreement. For more information regarding the DESRES Agreement, see "Business—Collaboration and License Agreement with D. E. Shaw Research, LLC."

We have not yet designated all of the compounds for which we will have this right of assignment, and thus, we do not yet know the scope of exclusivity we will enjoy under our patent rights for our product candidates.

After any work product is assigned to us, we will have the right to prepare, file, prosecute and maintain patents that cover such assigned work product. We also have the implicit right to defend patents that cover work product owned by us.

To date, much of the work product created under our agreement with D. E. Shaw Research has been created by D. E. Shaw Research and us, together, and is thus co-owned. We have the first right to prepare, file, prosecute, maintain and defend patents that cover work product created by D. E. Shaw Research and us, together. If we choose not to exercise those rights with respect to patents and patent applications that cover joint work product, D. E. Shaw Research will have the right to take over such activities, unless such rights are waived, as is the case for our co-owned SHP2 patent applications. The party that is preparing, filing, prosecuting and maintaining a patent that covers joint work product also has the right to enforce such patent against infringers.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation.

The degree of patent protection we require to successfully commercialize our product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our pending patent applications will issue, or that any of our pending patent applications that mature into issued patents will include claims with a scope sufficient to protect RLY-1971, RLY-4008 or our other product candidates. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned patent portfolio and any patent portfolio we may license in the future may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to our product candidates, including generic versions of such products.

We have licensed patent rights, and in the future may license additional patent rights, to or from third parties. For example, we have licensed our patent rights to our SHP2 program to Genentech. These licensed patent rights may be valuable to our business, and we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or medicines underlying such licenses. We cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. If any such licensors or licensees fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected.

Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications, with respect to either the same methods or formulations or the same subject matter, in either case that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in

some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to most of the pending patent applications covering our product candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. Patent and Trademark Office, or USPTO, have been significantly narrowed by the time they issue, if at all. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to maintain such competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party submission of prior art to the USPTO challenging the priority of an invention claimed within one of our patents, which submissions may also be made prior to a patent's issuance, precluding the granting of any of our pending patent applications. We may become involved in opposition, derivation, reexamination, inter parties review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others from whom we have obtained licenses to such rights.

Competitors may claim that they invented the inventions claimed in our issued patents or patent applications prior to us, or may file patent applications before we do. Competitors may also claim that we are infringing on their patents and that we therefore cannot practice our technology as claimed under our patents, if issued. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. With respect to intellectual property arising in the course of our collaboration with D. E. Shaw Research, disagreements between us and D. E. Shaw Research may impact our exclusive control of intellectual property important for protecting our product candidates and proprietary position. A loss of exclusivity, in whole or in part, could allow others to compete with us and harm our business.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, without payment to us, or could limit the duration of the patent protection covering our technology and product candidates. Such challenges may also result in our inability to manufacture or commercialize our product candidates without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if they are unchallenged, our owned patent portfolio and any patent portfolio we may license in the future may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to

circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. For example, a third party may develop a competitive product that provides benefits similar to one or more of our product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our product candidates, which would have a material adverse effect on our business.

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

In addition to the protection afforded by patents, we rely upon unpatented trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. With respect to the building of our proprietary compound library, we consider trade secrets and know-how to be our primary intellectual property. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our consultants and employees. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

Our trade secrets could otherwise become known or be independently discovered by our competitors. Competitors could purchase our product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' products, our competitive position could be adversely affected, as could our business.

Risks Related to Intellectual Property Litigation

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and frequent litigation regarding patents and other intellectual property rights. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference proceedings before the USPTO. Our competitors or other third parties may assert infringement claims against us, alleging that our products or technologies are covered by their patents. Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Many companies have filed, and continue to file, patent applications related to SHP2 inhibitors, FGFR2 inhibitors, and PI3K inhibitors. Some of these patent applications have already been allowed or issued, and others may issue in the future. Since these areas are competitive and of strong interest to pharmaceutical and biotechnology companies, there will likely be additional patent applications filed and additional patents granted in the future, as well as additional research and development programs expected in the future. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates, or the practice of our technology. If a patent holder believes our product or product candidate infringes on its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our owned patent portfolio and any patent portfolio we may license in the future may thus have no deterrent effect.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our product candidates and technology. We may choose to obtain a license, even in the absence of an action or finding of infringement. In either case, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby providing our competitors and other third parties access to the same technologies licensed to us. Without such a license, we could be forced, including by court order, to cease developing and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed such third-party patent rights. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our products in one or more foreign countries, which would have a materially adverse effect on our business.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate such technologies or features would have a material adverse effect on our business, and

may prevent us from successfully commercializing our product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which would have an adverse effect on our business, results of operations and financial condition.

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims. A court may disagree with our allegations, however, and may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the third-party technology in question. Further, such third parties could counterclaim that we infringe their intellectual property or that a patent we have asserted against them is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. In addition, third parties may initiate legal proceedings against us to assert such challenges to our intellectual property rights. The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Patents may be unenforceable if someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render any patents that may issue invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our future patents, should they issue, but that could nevertheless be determined to render our patents invalid.

An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our product candidates, we would lose at least part, and perhaps all, of the patent protection covering such product candidate. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. 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. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Risks Related to Enforcement of Our Intellectual Property Rights

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the patent laws of some foreign countries do not afford intellectual property protection to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. 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.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in the major markets for our product candidates, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

Risks Related to Third Party Intellectual Property

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

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our products. 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 on commercially reasonable terms, or our business could be harmed, possibly materially. Although we believe that licenses to these patents are available from these third parties on commercially reasonable terms, if we were not able to obtain a license, or were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

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

We expect our future license agreements will impose, various development, diligence, commercialization, and other obligations on us in order to maintain the licenses. In spite of our efforts, a future licensor might conclude that we have materially breached our obligations under such license agreements and seek to terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patent rights licensed thereunder fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

The agreements under which we may license intellectual property or technology from third parties may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on 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 licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

These and similar issues may arise with respect to our collaboration agreements, such as our DESRES Agreement. Our collaboration with D. E. Shaw Research is our key computational collaboration, and there can be no assurance that this collaboration will continue past the current term of the DESRES Agreement, on favorable terms or at all, or that at any time while the collaboration is in effect D. E. Shaw Research will provide any particular level of services or that the parties will operate under the agreement without disputes. These disputes may involve ownership or control of intellectual property rights, exclusivity obligations, diligence and payment obligations, for example.

The DESRES Agreement imposes certain exclusivity obligations on us during the term of the agreement with respect to Category 2 targets, and certain exclusivity obligations on D. E. Shaw Research during and after the term of the agreement. While we have some degree of control over how we designate various targets under the DESRES Agreement, D. E. Shaw Research has some degree of control over such designations as well, and our exclusivity obligations limit or delay our ability to conduct research on selected targets with third parties.

Under the DESRES Agreement, D. E. Shaw Research controls the rights to its technology, we control the rights to certain compounds, and we jointly own with D. E. Shaw Research any other work product created by D. E. Shaw Research and us. Any work product we jointly own with D. E. Shaw Research and any other information that we or D. E. Shaw Research share is subject to a non-exclusive cross-license between us and D. E. Shaw Research, subject to certain exceptions. In some instances, D. E. Shaw Research is required to assign to us some of the work product

created by D. E. Shaw Research. Disputes may arise between us and D. E. Shaw Research, as well as any future potential collaborators, regarding intellectual property subject to the DESRES Agreement. If disputes over intellectual property that we co-own or we own individually prevent or impair our ability to maintain our current collaboration arrangements on acceptable terms, or undermine our ability to successfully control the intellectual property necessary to protect our product candidates, we may be unable to successfully develop and commercialize the affected product candidates. Uncertainties or disagreements around our rights under any such intellectual property may undermine our ability to partner our programs with third parties.

In addition, the DESRES Agreement is complex and certain provisions may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could be adverse to us, for example by narrowing what we believe to be the scope of our rights to certain intellectual property, or increasing what we believe to be our financial or other obligations under the DESRES Agreement, and any such outcome could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Intellectual Property Laws

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a “first to file” system. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

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. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce rights in our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce any patents that we may obtain in the future.

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 product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
- we or our licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future;
- we or our licensors or 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;
- it is possible that our present or future pending patent applications (whether owned or licensed) will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Related to Government Regulation

Risks Related to Regulatory Approval

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

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping 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, establishment registration and listing, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- clinical trial holds
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory

compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

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

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about approved prescription drug products. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of regulated products for off-label uses and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

European data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

In the event we decide to conduct clinical trials or continue to enroll subjects in our ongoing or future clinical trials, we may be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

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

We 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 regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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

reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we may intend to charge for our products will also be subject to approval.

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

In connection with the clinical development of our product candidates for certain indications, we may engage third parties to develop or obtain access to *in vitro* companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our product candidates. Further, the FDA has indicated that if we continue RLY-4008 in a specific biomarker-defined population, a companion diagnostic device will be required to ensure its safe and effective use. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA and comparable foreign regulatory authorities regulate *in vitro* companion diagnostics as medical devices and, under that regulatory framework, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

We intend to rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our therapeutic candidates.

Risks Related to Anti-bribery, Anti-corruption and Other Government Regulations

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

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly

reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

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

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, which are collectively referred to as 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.

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

Although we do not currently have any products on the market, once we begin commercializing our product candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third-party payors 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 that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to

violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. 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 federal False Claims Act or federal civil money penalties. On November 20, 2020, the Office of Inspector General, or OIG, finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. These rules (with exceptions) became effective January 19, 2021. We continue to evaluate what effect, if any, these rules will have on our business;

- the federal civil and criminal false claims and civil monetary penalties laws, including the federal False Claims Act, or FCA, imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the Affordable Care Act, require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Department of Health and Human Services information related to transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests of such physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Further, many state laws governing the privacy and security of health information in certain circumstances, differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our

business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Related to Regulatory Review of Certain Drug Development Designations

We may seek priority review designation for one or more of our other product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

We may seek orphan drug designation for certain of 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 certain of our product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is 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 of 200,000 or more 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 Europe, the European Commission, upon the recommendation of the EMA's Committee for Orphan Medicinal Products, grants orphan drug designation to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers.

Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. 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 so that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the drug from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes 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 indication 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 or if another drug with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care. 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 our 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.

Breakthrough therapy designation and fast track designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review or approval process, and each designation does not increase the likelihood that any of our product candidates will receive marketing approval in the United States.

We may seek a breakthrough therapy designation for some of 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 existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy 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 a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

Accelerated approval by the FDA, even if granted for our FGFR2 program or our PI3K program or any other future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek accelerated approval of our FGFR2 program or our PI3K program and for future product candidates. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate 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, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving

accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate FDA approval.

Risks Related to Healthcare Legislative Reform

The FDA, the EMA and other regulatory authorities may implement additional regulations or restrictions on the development and commercialization of our product candidates, and such changes can be difficult to predict.

The FDA, the EMA and regulatory authorities in other countries have each expressed interest in further regulating biotechnology products. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical trials of products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

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

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current or future product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Affordable Care Act, or the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the United States pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D. Since then, the ACA risk adjustment program payment parameters have been updated annually.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court. Additionally, the previous Administration issued various Executive Orders which

eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. In December 2018, the Centers for Medicare & Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of the federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then, the ACA risk adjustment program payment parameters have been updated annually. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business, especially given the new administration.

Moreover, on January 22, 2018, a continuing resolution on appropriations for fiscal year 2018 was approved that delayed the implementation of certain ACA-mandated fees, including the so called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices; however on December 20, 2019, the Further Consolidated Appropriations Act (H.R. 1865) was signed into law, which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future. The Bipartisan Budget Act of 2018, also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, CMS has recently published a final rule that would give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken; however, pursuant to the CARES Act and subsequent legislation, these reductions have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. The American Taxpayer Relief Act of 2012 among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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 U.S. Congressional inquiries and proposed 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. At the federal level, the previous administration’s budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the previous administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the previous administration also released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of product candidates paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow

Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. It is unclear whether the current administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021.

In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the FYs 2019 and 2018 reimbursement formula on specified covered outpatient drugs, or SCODs. The court ruled this change was not an "adjustment" which was within the Secretary's discretion to make but was instead a fundamental change in the reimbursement calculation. However, most recently, on July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court's decision and found that the changes were within the Secretary's authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), but was denied on October 16, 2020. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any.

On July 24, 2020 and September 13, 2020, the previous administration announced several executive orders related to prescription drug pricing that sought to implement several of the administration's proposals. In response, the FDA released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada, as further discussed below. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. The Interim Final Rule has not been finalized and is subject to revision and challenge. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Implementation of November 20, 2020 final Rule will be delayed until at least January 1, 2023. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

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

Further, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its product candidates available to eligible patients as a result of the Right to Try Act.

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 current or future product candidates or additional pricing pressures. In

particular any policy changes through CMS as well as local state Medicaid programs could have a significant impact on our business in light of the higher proportion of SCD patients that utilize Medicare and Medicaid programs to pay for treatments.

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

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

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

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

Recent federal legislation and actions by federal, state and local governments may permit reimportation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results.

We may face competition in the United States for our development candidates and investigational medicines, if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the United States, the Medicare Modernization Act, or MMA, contains provisions that call for the promulgation of regulations that expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. Further, the MMA provides that these changes to U.S. importation laws will not take effect, unless and until the Secretary of the HHS certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the Secretary of the HHS made such certification to Congress, and on October 1, 2020, FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability.

Risks Related to the Regulatory Agency Review Process

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical government employees and stop critical activities. Separately, in response to the COVID-19 pandemic since March 2020, foreign and domestic inspections by the FDA have largely been on hold with FDA announcing plans in July 2020 to resume prioritized domestic inspections. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, the FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. Additionally, as of June 23, 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals. On July 16, 2020, the FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions, the FDA is unable to complete such required inspections during the review period. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Employee Matters and Managing Growth

Risks Related to Employee Matters

Our future success depends on our ability to retain key executives and experienced scientists and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical and business development expertise of the principal members of our management, scientific and clinical team. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees, including temporary loss due to illness, could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

In particular, we have experienced a very competitive hiring environment in Cambridge, Massachusetts, where we are headquartered. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

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

Risks Related to Growth

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

As of February 28, 2021, we had 159 full-time employees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly as we function as a public company and in the areas of product development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to

implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Risks Related to Business Disruptions

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our or related parties' cyber security.

Given our limited operating history, we are still in the process of implementing our internal security measures. Our internal computer systems and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses and unauthorized access. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidate or any future product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidate or any future product candidates could be hindered or delayed. In addition, in response to the ongoing COVID-19 pandemic, part of our workforce is currently working remotely. This could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological 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.

Our current operations are located in Massachusetts; and we or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are located in Massachusetts. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, including any potential effects from the current global spread of COVID-19, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Natural disasters or pandemics such as the COVID-19 outbreak could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. For example, we have instituted a temporary work from home policy for non-essential office personnel and it is possible that this could have a negative impact on the execution of our business plans and operations. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure our investors that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities or the manufacturing facilities of our third-party contract manufacturers are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Common Stock

Risks Related to Our Status as an “Emerging Growth Company” and “Smaller Reporting Company”

We are an “emerging growth company” as defined in the JOBS Act and a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, and may avail ourselves of reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of our IPO; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- providing only two years of audited financial statements in addition to any required unaudited interim financial statements and a correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;

- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens. In particular, we have provided only two years of audited financial statements and have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early. Changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations. In addition, our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as a "smaller reporting company" or an "emerging growth company," we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile and may decline.

Risks Related to Volatility in the Price of Our Common Stock

The trading price of our common stock is likely to be highly volatile. Securities class action or other litigation involving our company or members of our management team could also substantially harm our business, financial condition and results of operations.

Our stock price is likely to be 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:

- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- 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 any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- 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;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

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

Risks Related to Insider Control

Our executive officers, directors, principal stockholders and their affiliates exercise significant control over our company, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

As of March 15, 2021, the holdings of our executive officers, directors, principal stockholders and their affiliates, including entities affiliated with SoftBank Vision Fund, Third Rock Ventures and FMR LLC represented beneficial ownership, in the aggregate, of approximately 49.6% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and control the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. These stockholders may have interests, with respect to their common stock, that are different from those of our public market investors and the concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Risks Related to Tax

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the IRC, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in the ownership of its equity over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2020, we had federal net operating loss carryforwards of approximately $174.0 million, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made and changes are likely to continue to occur in the future.

For example, the Tax Cuts and Jobs Act, or Tax Act, was enacted in 2017 and made significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses from taxable years beginning after December 31, 2017 to 80% of current year taxable income and the elimination of net operating loss carrybacks generated in taxable years ending after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), and the modification or repeal of many business deductions and credits. In addition, on March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, which, among other things, suspends the 80% limitation on the deduction for net operating losses in taxable years beginning before January 1, 2021, permits a 5-year carryback of net operating losses arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally caps the limitation on the deduction for net interest expense at 50% of adjusted taxable income for taxable years beginning in 2019 and 2020.

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Risks Related to Dividends

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Risks Related to Operating as a Public Company

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

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and

challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

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

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

Risks Related to Our Charter and Bylaws

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

Our fourth amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of the stockholders may be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office, and special meetings of stockholders may not be called by any other person or persons;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds (2/3) of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than a majority of all outstanding shares of our voting stock to amend any bylaws by stockholder action and not less than two-thirds (2/3) of all outstanding shares of our voting stock to amend specific provisions of our fourth amended and restated certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval, which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our fourth amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of or based on a breach of a fiduciary duty owed by any director, officer or other employee of ours to us or our stockholders; (3) any action asserting a claim pursuant to any provision of the Delaware General Corporation Law, our fourth amended and restated certificate of incorporation or our amended and restated bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

We recognize that the Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Risks Related to Market Analysts

If securities analysts do not 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 will rely in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our stock downgrade their evaluations of our stock or publishes inaccurate or unfavorable research about our business, the trading price of our

stock may decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters is located in Cambridge, Massachusetts, where we lease and occupy approximately 46,631 square feet of office and laboratory space. The current term of our Cambridge lease expires April 30, 2029, with an option to extend the term five additional years with 12 – 15 months' notice at agreed upon market rate.

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 may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol "RLAY" on the NASDAQ Global Market and has been publicly traded since July 16, 2020. Prior to this time, there was no public market for our common stock.

Holders of Our Common Stock

As of February 26, 2021, there were approximately 61 holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

Unregistered Sales of Equity Securities and Use of Proceeds

Set forth below is information regarding stock options granted by us and exercised during the period covered by this Annual Report on Form 10-K that were not registered under the Securities Act of 1933, as amended, or the Securities Act. Included is the consideration, if any, we received for such shares and options and information relating to the section of the Securities Act under which exemption from registration was claimed.

From January 1, 2020 to the closing of our IPO on July 20, 2020, we granted options to purchase an aggregate of 2,492,458 shares of common stock, with exercise prices ranging from $5.22 to $14.06 per share, to directors, employees and consultants pursuant to our 2016 Stock Option and Grant Plan, as amended, or the 2016 Plan. During such period, 280,548 shares of common stock were issued for gross proceeds of $1.1 million upon the exercise of stock options pursuant to the 2016 Plan.

No underwriters were involved in the foregoing issuances of securities. The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act as transactions by an issuer not involving a public offering or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. All recipients either received adequate information about us or had access, through employment or other relationships, to such information. On July 17, 2020, we filed a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to our equity compensation plans.

Recent Sales of Unregistered Equity Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. Reserved

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. 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 in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage, precision medicines company transforming the drug discovery process with an initial focus on enhancing small molecule therapeutic discovery in targeted oncology. Our company is built upon unparalleled insights into protein motion and how this dynamic behavior relates to protein function. We built our Dynamo platform to integrate an array of leading edge experimental and computational approaches, which allows us to apply our understanding of protein structure and motion to drug discovery.

We are advancing a pipeline of medicines to address targets in precision oncology, including our lead product candidates, RLY-1971 and RLY-4008, as well as our PI3Kα mutant selective program, or the RLY-PI3K1047 program. We initiated a Phase 1 clinical trial for RLY-1971, our inhibitor of Src homology region 2 domain-containing phosphatase-2, or SHP2, in patients with advanced solid tumors in the first quarter of 2020. In December 2020, we entered into a global collaboration and license agreement, or the Genentech Agreement, with Genentech, Inc., a member of the Roche Group, or Genentech, for the development and commercialization of RLY-1971. We initiated a first-in-human clinical trial for RLY-4008, our inhibitor of fibroblast growth factor receptor 2, or FGFR2, enriched for patients with advanced solid tumors having oncogenic FGFR2 alterations in the third quarter of 2020. We anticipate the RLY-PI3K1047 program, our program for molecules targeting cancer-associated mutant variants of phosphoinostide 3-kinase alpha, or PI3Kα, to be in Investigational New Drug, or IND, enabling studies in 2021. While our initial focus is on precision oncology, we believe our Dynamo platform may also be broadly applied to other areas of precision medicine, such as genetic disease. In addition to the three product candidates described above, we have five discovery stage programs across both precision oncology and genetic disease. We are focused on using the novel insights derived from our approach to transform the lives of patients suffering from debilitating and life-threatening diseases through the discovery, development and commercialization of our therapies.

We were incorporated in May 2015. We have devoted substantially all of our resources to developing our lead product candidates, developing our innovative experimental and computational approaches on protein motion, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. To date, we have principally financed our operations through private placements of preferred stock, convertible debt and proceeds from our initial public offering, or IPO, discussed below. Additionally, in January 2021, we received an upfront payment of $75.0 million in connection with the Genentech Agreement.

On July 20, 2020, we closed our IPO and issued 23,000,000 shares of our common stock at a price of $20.00 per share for net proceeds of $425.3 million, after deducting underwriting discounts and commissions of $32.2 million and expenses of $2.5 million. In connection with our IPO, all shares of Series A, Series B and Series C convertible preferred stock converted into 61,992,534 shares of common stock. Prior to our IPO, we had received gross proceeds of approximately $520.0 million from sales of our preferred stock and our issuance of convertible debt.

In December 2020, we entered into the Genentech Agreement with Genentech, for the development and commercialization of RLY-1971. Under the terms of the Genentech Agreement, we received $75.0 million in an upfront payment and are eligible to receive $25.0 million in near-term payments; and, if we do not opt into a U.S. profit/cost share, up to $695.0 million in additional development, commercialization and sales-based milestones for RLY-1971; and tiered royalties on annual global net sales (on a country-by-country basis), anticipated to be in the low-to-mid-teens, subject to reductions in certain circumstances. Additionally, we are eligible to receive additional royalties in the event of regulatory approval of RLY-1971 and Genentech's compound, GDC-6036, that directly

binds to and inhibits KRAS ^{G12C}, in combination. We have the right to opt-in to a 50/50 U.S. profit/cost share and if we do opt into the U.S. profit/cost share, we are eligible to receive up to $410 million in additional commercialization and sales-based milestones for RLY-1971 outside of the U.S. and tiered royalties on annual net sales outside of the U.S. (on a country-by-country basis), anticipated to be in the low-to-mid-teens, subject to reduction in certain circumstances. We also retain the right to develop RLY-1971 in combination with our FGFR2 and PI3Kα programs.

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as contributing to significant volatility and negative pressure on the U.S. economy and in financial markets. Efforts to contain the spread of the COVID-19 pandemic have intensified and the United States, Europe and Asia have implemented severe travel restrictions, social distancing requirements, stay-at-home orders and have delayed the commencement of non-COVID-19-related clinical trials, among other restrictions.

While we are currently continuing the clinical trials we have underway, we expect that COVID-19 precautions may directly or indirectly impact the timeline for some of our clinical trials. To date, we have been able to continue to enroll our patients in first-in-human clinical trials for RLY-1971 and RLY-4008, and we currently do not anticipate any interruptions in clinical enrollment. However, we are continuing to assess the potential impact of the COVID-19 pandemic on our current and future business and operations, including our expenses and clinical trials, as well as on our industry and the healthcare system.

Since our inception, we have incurred significant operating losses on an aggregate basis. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net losses were $52.4 million and $75.3 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $404.2 million. These losses have resulted primarily from costs incurred in connection with research and development activities, licensing and patent investment and general and administrative costs associated with our operations. We expect to continue to incur significant expenses, including the costs of operating as a public company, and generate increasing operating losses for at least the next several years.

We anticipate that our expenses will increase substantially if and as we:

- conduct our current and future clinical trials of RLY-4008, additional preclinical research and development of our RLY-PI3K1047 program, and other early-stage programs;
- initiate and continue research and preclinical and clinical development of our other product candidates;
- seek to identify additional product candidates;
- pursue marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- require the manufacture of larger quantities of our product candidates for clinical development and potentially commercialization;
- obtain, maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other drugs and technologies;
- hire and retain additional clinical, regulatory, quality and scientific personnel;
- build out new facilities or expand existing facilities to support our ongoing development activity; and
- add operational, financial and management information systems and personnel, including personnel to support our drug development, any future commercialization efforts and our operations as a public company.

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

As a result, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed, on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce or terminate our operations.

We believe our cash, cash equivalents and investments of $678.1 million as of December 31, 2020, together with the $75.0 million upfront payment received in January 2021 in connection with the Genentech Agreement, will enable us to fund our operating expenses and capital expenditure requirements into 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We will need to raise additional capital in the future to continue developing the drugs in our pipeline and to commercialize any approved drug. We may seek to obtain additional financing in the future through the issuance of our common stock, through other equity or debt financings or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan. See “—Liquidity and Capital Resources.”

Components of our Results of Operations

Revenue

For the year ended December 31, 2020, our revenue consists solely of amounts related to the Genentech Agreement. We recognize our revenue as the performance obligations are satisfied under the agreement.

Operating Expenses

Our operating expenses since inception have consisted solely of research and development costs and general and administrative costs.

Research and Development Expenses

Research and development expenses include:

- salaries, benefits and other employee related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and other vendors that conduct our clinical trials and preclinical activities;
- costs of acquiring, developing and manufacturing clinical trial materials and lab supplies;
- costs related to compliance with regulatory requirements; and
- facility costs, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies.

We expense research and development costs as the services are performed or the goods are received. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid expenses or accrued research and development expenses.

We began tracking external development costs by program on January 1, 2020 for programs that have entered clinical trials. We do not allocate internal costs, facilities costs or other overhead costs to specific programs. The following summarizes our costs based on their status in development:

	Year Ended December 31, 2020
External costs for programs in clinical trials	$ 7,447
External costs for programs in discovery and pre-clinical studies	42,431
External costs for platform research and other research and development activities	11,544
Employee related expenses	38,440
Total research and development expenses	$ 99,862

Our most advanced development programs, RLY-1971 and RLY-4008, are enrolling patients in first-in-human clinical trials. Programs in discovery and pre-clinical stages include our RLY-P13K1047 program as well as other earlier stage programs. Costs incurred for these programs include costs incurred to support our discovery research and translational science efforts up to the initiation of first-in-human clinical development. Platform research and other research and development activities include costs that are not specifically allocated to active product candidates, including facilities costs, depreciation expense and other costs. Employee related expenses includes salary, wages, stock-based compensation and other costs related to our personnel, which are not allocated to specific programs or activities.

We cannot determine with certainty the duration and costs of future clinical trials and future development costs, if, when or to what extent we will generate revenue from the commercialization and sale of any our product candidates for which we obtain marketing approval or our other research and development costs. We may never succeed in obtaining marketing approval for any of our product candidates.

The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of our preclinical development activities, any future clinical trials of RLY-4008, our RLY-PI3K1047 program or other product candidates and other research and development activities that we may conduct;
- uncertainties in clinical trial design and patient enrollment or drop out or discontinuation rates;
- establishing an appropriate safety and efficacy profile with IND-enabling studies;
- the initiation and completion of future clinical trial results;
- the timing, receipt and terms of any approvals from applicable regulatory authorities including the U.S. Food and Drug Administration, or FDA, and non-U.S. regulators;
- significant and changing government regulation and regulatory guidance;
- potential additional studies requested by regulatory agencies;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;

- the impact of any business interruptions to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers or other vendors resulting from the COVID-19 pandemic or a similar public health crisis;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase for the foreseeable future as we continue clinical trials of RLY-4008, the development of our RLY-PI3K1047 program and to identify and develop additional product candidates.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant trial delays due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our general and administrative personnel headcount to support personnel in research and development and to support our operations generally as we increase our research and development activities and activities related to the potential commercialization of our product candidates. We also expect to incur increased expenses associated with operating as a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission, or SEC, requirements, director and officer insurance costs, and investor and public relations costs.

Other Income, Net

Other income, net primarily consists of interest income related to interest earned on our cash, cash equivalents and investments.

Income Taxes

Since our inception in 2015, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in any year or for our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2020, we had federal NOL carryforwards of $174.0 million available to reduce taxable income, of which $43.1 million expire beginning in 2035 and $130.9 million do not expire. We have state NOL carryforwards of $192.3 million as of December 31, 2020 available to reduce future state taxable income, which expire at various dates beginning in 2035.

As of December 31, 2020, we also had federal and state research and development tax credit carryforwards of $8.1 million and $2.7 million, respectively, which begin to expire in 2035 and 2030, respectively.

Results of Operations

Comparison of years ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019:

	Year Ended December 31,		
	2020	2019	Change
	(in thousands)		
Revenue	$ 82,654	$ —	$ 82,654
Operating expenses:			
Research and development	$ 99,862	$ 70,306	$ 29,556
General and administrative	38,588	13,742	24,846
Total operating expenses	138,450	84,048	54,402
Loss from operations	(55,796)	(84,048)	28,252
Interest income and other expense	3,384	8,743	(5,359)
Net loss	$ (52,412)	$ (75,305)	$ 22,893

Revenue

We recognized revenue of $82.7 million for the year ended December 31, 2020 in connection with the Genentech Agreement related to the satisfaction of our performance obligation for the license transfer. We did not recognize any revenue for the year ended December 31, 2019.

Research and Development Expenses

	Year Ended December 31,		
	2020	2019	Change
	(in thousands)		
Employee related expenses	$ 38,440	$ 19,914	$ 18,526
Outside and consulting services	46,009	34,585	11,424
Depreciation of laboratory equipment	2,889	2,410	479
Laboratory supplies and other costs	6,754	7,289	(535)
Facilities and other allocated expenses	5,770	6,108	(338)
Total research and development expenses	$ 99,862	$ 70,306	$ 29,556

Research and development expenses were $99.9 million for the year ended December 31, 2020 compared to $70.3 million for the year ended December 31, 2019. The increase of $29.6 million was primarily due to $18.5 million of increased employee related costs, including $12.0 million of additional share-based compensation expense, primarily due to increases in our stock price and increased headcount, and $11.4 million in increased outside and consulting expenses associated with our clinical and pre-clinical candidates.

General and Administrative Expenses

General and administrative expenses were $38.6 million for the year ended December 31, 2020 compared to $13.7 million for the year ended December 31, 2019. The increase of $24.8 million was primarily due to $19.2 million of increased employee related costs, including $15.5 million of additional share-based compensation expense, primarily due to increases in our stock price and increased general and administrative headcount to support the growth of our organization, and $5.2 million of other general and administrative expenses primarily attributed to increases in insurance, legal and other expenses.

Other Income (Expense), Net

Other income, net, was $3.4 million for the year ended December 31, 2020 compared to $8.7 million for the year ended December 31, 2019 due primarily to decreases in interest rates and lower investment amounts.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of any product candidates for several years, if ever. On July 20, 2020, we closed our IPO and issued 23,000,000 shares of common stock for net proceeds of $425.3 million. Prior to our IPO, we received gross proceeds of $520.0 million from sales of our preferred stock and our issuance of convertible debt. As of December 31, 2020, we had cash, cash equivalents and investments of $678.1 million. In January 2021, we received an upfront payment of $75.0 million from Genentech pursuant to the Genentech Agreement.

Cash Flows

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

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Cash used in operating activities	$ (102,489)	$ (66,133)
Cash provided by (used in) investing activities	81,672	(319,024)
Cash provided by financing activities	426,509	5,606
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 405,692	$ (379,551)

Operating Activities.

During the year ended December 31, 2020, operating activities used $102.5 million of cash, primarily resulting from our net loss of $52.4 million and cash used by changes in our operating assets and liabilities of $85.2 million, partially offset by non-cash charges of $35.1 million. Net cash used by changes in our operating assets and liabilities of $85.2 million during the year ended December 31, 2020 consisted of increases of $75.0 million in accounts receivable, $7.7 million in contract assets, and $4.7 million in prepaid expenses and other current assets, offset by an increase of $2.0 million in accrued expenses and other liabilities. The increase in accounts receivable and contract assets was due to the upfront payment received and revenue recognized in connection with the Genentech Agreement. The increase in prepaid expenses was primarily due to increases in prepaid license fees and insurance. The increase in accrued expenses and other current liabilities was largely due to an increase in external research and development costs.

During the year ended December 31, 2019, operating activities used $66.1 million of cash, primarily resulting from our net loss of $75.3 million, partially offset by non-cash charges of $4.9 million and cash provided by changes in our operating assets and liabilities of $4.3 million. Net cash provided by changes in our operating assets and liabilities of $4.3 million during the year ended December 31, 2019 consisted of an increase of $5.2 million in accounts payable, accrued expenses and other current liabilities as well as a decrease of $1.2 million of operating lease assets, net, partially offset by an increase of $2.1 million in prepaid expenses and other current assets. The increase in accounts payable, accrued expenses and other current liabilities was largely due to an increase in external research and development costs. The increase in prepaid expenses and other current assets was due to an increase in external research and development costs.

Investing Activities.

During the year ended December 31, 2020, investing activities provided $81.7 million, consisting primarily of $83.6 million of net investment proceeds from maturities offset by $1.9 million for the purchase of property and equipment.

During the year ended December 31, 2019, investing activities used $319.0 million, consisting primarily of $311.0 million of net investment purchases and $8.0 million for the purchase of property and equipment.

Financing Activities.

During the year ended December 31, 2020, net cash provided by financing activities was $426.5 million, consisting of net proceeds from the issuance of common stock upon the closing of our IPO of $425.3 million and proceeds from stock option exercises of $1.2 million.

During the year ended December 31, 2019, net cash provided by financing activities was $5.6 million, consisting of net proceeds from our sales of Series C convertible preferred stock of $5.0 million and proceeds from the exercise of stock options of $0.6 million.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing clinical development activities related to the potential clinical development activities of RLY-4008 and the ongoing pre-clinical development activities of our RLY-PI3K1047 program. In addition, we are now incurring additional costs associated with operating as a public company. We expect that our expenses will increase substantially as discussed in more detail in "—Overview" above.

As of December 31, 2020, we had cash, cash equivalents and investments of $678.1 million. We believe that our existing cash, cash equivalents and investments, together with the $75.0 million upfront payment received in January 2021 in connection with the Genentech Agreement, will enable us to fund our operating expenses and capital expenditure requirements into 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with the development of RLY-4008, our RLY-PI3K1047 programs and other product candidates and programs, and because the extent to which we may enter into collaborations with third parties for the development of our product candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including:

- the impact of any business interruptions to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers or other vendors, resulting from the COVID-19 pandemic or similar public health crisis;
- the scope, progress, results and costs of our current and future clinical trials of RLY-4008 and additional preclinical research of our RLY-PI3K1047 program;
- the scope, progress, results and costs of drug discovery, preclinical research and clinical trials for our other product candidates;
- the number of future product candidates that we pursue and their development requirements;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the success of any existing or future collaborations that we may enter into with third parties;

- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates, such as our collaboration with Genentech;
- the achievement of milestones or occurrence of other developments that trigger payments under any existing or future collaboration agreements, if any;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under any existing or future collaboration agreements, if any;
- the costs and timing of future commercialization activities, including drug sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval, to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of any collaborator that we may have at such time;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and our research and development activities; and
- the costs of operating as a public company.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any product candidates or generate revenue from the sale of any product candidate for which we may obtain marketing approval. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. Additional debt or preferred equity financing, if available, may involve agreements that include restrictive covenants that may limit our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends, which could adversely impact our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute your ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or collaborations, strategic alliances or licensing arrangements with third parties when needed, we may be required to delay, limit, reduce and/or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

On June 15, 2020, we entered into an Amended and Restated Collaboration and License Agreement, or DESRES Agreement, with D. E. Shaw Research, LLC, or D. E. Shaw Research, extending the term and otherwise modifying the terms of the Collaboration and License Agreement originally entered into on August 17, 2016. The DESRES Agreement provides that the parties will jointly conduct research efforts with the goal of identifying and developing product candidates. On a product-by-product basis, we have agreed to pay D. E. Shaw Research milestone payments upon the achievement of certain development and regulatory milestone events for products we develop under the

DESRES Agreement that are directed to a Category 1 Target or any target that was a Category 1 Target. Such payments for achievement of development and regulatory milestones total up to $7.3 million in the aggregate for each of the first three products we develop, and up to $6.3 million in the aggregate for each product we develop after the first three. In addition, we are obligated to pay D. E. Shaw Research royalty payments as defined in the DESRES Agreement. We assessed the milestone and royalty events under the DESRES Agreement as of December 31, 2020 and 2019, respectively, and concluded that $1.5 million was due related to the execution of the Genentech Agreement as of December 31, 2020 and no such payments were due as of December 31, 2019.

The DESRES Agreement extended the term of the original agreement to August 16, 2025 and increased the annual fee from $1.0 million to $7.9 million, commencing on August 16, 2020. The DESRES Agreement automatically renews for successive one year periods unless either party provides at least one year notice of non-renewal, and the annual fee during each of the one year renewal terms is subject to the mutual agreement of us and D. E. Shaw Research.

We also have certain research and license arrangements with other third parties, which provide us with research services with the goal of identifying and developing product candidates until all payment obligations by us to the third party have expired. We have the right to terminate these agreements with a reasonable period of notice. We are also obligated to pay development milestone payments for up to four targets, each in the range of $4.0 million to $7.0 million, upon the achievement of certain specified contingent events. We assessed the milestones as of December 31, 2020 and 2019 and concluded no such milestone payments were due.

We enter into contracts in the normal course of business with CROs and CMOs for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts do not contain any minimum purchase commitments and are cancelable by us upon prior notice of 30 days. Payments due upon cancelation consist only of payments for services provided and expenses incurred up to the date of cancelation.

In December 2017, we entered into a facility lease agreement for approximately 44,336 square feet of office and laboratory space at 399 Binney Street, Cambridge, Massachusetts, which was increased to 44,807 square feet in January 2018. We gained control of the space in January 2019 and the lease expires in April 2029, subject to certain renewal options, which have not been included in our right of use asset and liability. In September 2020, we entered into an amendment to our existing facility lease agreement to expand the leased area by approximately 1,824 square feet of office space at 399 Binney Street, Cambridge, Massachusetts. The amendment commenced in October 2020 and expires in April 2029, subject to certain renewal options.

We provided a letter of credit in connection with our facility lease agreement in the amount of $878 with a financial institution, which expires September 30, 2028.

For more information, see Note 13, *Commitments and Contingencies*, and Note 14, *Leases*, of the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including expenses, clinical trials and research and development costs, will

depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international markets. We have made estimates of the impact of COVID-19 within our financial statements and there may be changes to those estimates in future periods. Actual results could differ from our estimates.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We account for revenue recognition in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, or 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 the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity 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 entity satisfies a 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 the contract and determine those that are performance obligations. We then determine the transaction price and allocate it to the performance obligations using the relative selling price model. As part of the accounting for these arrangements, we must use significant judgment to determine: (a) the number of performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above, including the determination of whether milestones or other variable consideration should be included in the transaction price; and (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of the transaction price in step (iv) above.

We utilize key assumptions and judgments to determine the stand-alone selling price for each performance obligation, which may include discounted cash flow models, evaluation of comparable transactions, pricing considered in negotiating the transaction and estimated costs, to determine how the transaction price is allocated among the performance obligations. We use judgment to determine whether milestones or other variable consideration should be included in the transaction price. For revenue-based royalties, including milestone payments based on the level of sales, we will include royalties in the transaction price at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty is allocated has been satisfied (or partially satisfied). As part of management's evaluation of the transaction price, we consider numerous factors, including whether the achievement of the milestones is outside of our control, contingent upon the efforts of others or subject to the risks of success. If we conclude it is probable that a significant revenue reversal would not occur, the associated milestone payment is included in the transaction price. Milestone payments that are not within our control, such as regulatory approvals, are generally not considered probable until those milestones are achieved. We re-evaluate the transaction price, including estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Once the performance obligations are identified, the transaction price is allocated to each performance obligation based on the relative stand-alone selling price. 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, either at a point in time or over time. If the performance obligation is satisfied over time, we recognize revenue based on the use of either an output or input method.

As of December 31, 2020, we had one collaboration and license agreement with Genentech, which we entered into on December 11, 2020.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development and manufacturing expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research activities on our behalf and conducting preclinical studies and clinical trials on our behalf;
- investigative sites or other service providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing and development and distribution of preclinical and clinical supplies.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract, which may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We measure stock options and other stock-based awards granted to employees, directors and non-employees based on their fair value on the date of grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. We recognize the impact of forfeitures on stock-based compensation expense as forfeitures occur.

We issued certain options with performance-based vesting conditions whereby the service inception date preceded the accounting grant date and therefore we applied variable accounting for the awards until the fair value of the awards was known on the accounting grant date. The board of directors approved the commencement of vesting for all such awards in 2020, therefore we no longer apply variable accounting as of December 11, 2020.

We estimate the fair value of each stock option grant on the date of grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield.

Prior to our IPO, the estimated fair value of our common stock was determined by our board of directors, or compensation committee thereof, as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. Historically, these independent third-party valuations of our equity instruments were performed contemporaneously with identified value inflection points.

These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or the Practice Aid. The Practice Aid identifies various available methods for allocating the enterprise value across classes of series of capital stock in determining the fair value of our common stock at each valuation date.

Following our IPO, in connection with our accounting for granted stock options and other awards we may grant, the fair value of our common stock is determined based on the quoted market price of our common stock.

Emerging Growth Company and Smaller Reporting Company Status

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an "emerging growth company," or an EGC, can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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

Interest rate risk

We are exposed to market risk related to changes in interest rates of our investment portfolio of cash equivalents and investments. As of December 31, 2020, our cash equivalents consisted of money market funds. As of December 31, 2020, our investments consisted of investments in United States Treasury Bills, United States Treasury Bonds and agency bonds that have contractual maturities of less than two years. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. The fair value of our marketable securities is subject to change as a result of potential changes in market interest rates, including changes resulting from the impact of the COVID-19 pandemic. The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. As of December 31, 2020 and 2019, we estimate that such hypothetical 100 basis point adverse movement would not result in a material impact to our consolidated results of operations.

As of December 31, 2020, we had no debt outstanding and are therefore not exposed to interest rate risk with respect to debt.

Foreign currency exchange risk

All of our employees and our operations are currently located in the United States and 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 that permit us to satisfy our payment obligations in U.S. dollars (at prevailing exchange rates) but have underlying payment obligations denominated in foreign currencies, including the Euro. 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 financial statements, and we do not have 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 for the years ended December 31, 2020 and 2019.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, as incorporated into Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K, by reference.

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

None.

Item 9A. Controls and Procedures.

We have established disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial officer (our Senior Vice President, Finance), to allow timely decisions regarding required disclosure. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management has evaluated, with the participation of our Chief Executive Officer and Senior Vice President, Finance, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on that evaluation, our Chief Executive Officer and Senior Vice President, Finance have concluded that, as of December 31, 2020, our disclosure controls and procedures were effective.

Internal Control over Financial Reporting

Management's Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

As a result of the COVID-19 pandemic, many of our employees are working remotely. We have not identified any material changes in our internal control over financial reporting as a result of these changes to the working environment, in part because our internal control over financial reporting was designed to operate in a remote working environment. We are continually monitoring and assessing the COVID-19 situation to determine any potential impacts on the design and operating effectiveness of our internal controls over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2021 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

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

The information required by this Item 12 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The Exhibit Index is incorporated herein by reference.

Item 16. Form 10-K Summary

The Company has elected not to include summary information.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Relay Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Relay Therapeutics, Inc. (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

/s/ Ernst & Young

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

Boston, Massachusetts
March 25, 2021

Relay Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 447,646	$ 41,954
Investments	230,415	313,862
Accounts receivable	75,000	—
Contract asset	7,654	—
Prepaid expenses and other current assets	9,385	4,720
Total current assets	770,100	360,536
Property and equipment, net	6,250	8,094
Operating lease assets	22,579	23,560
Restricted cash	878	878
Other assets	22	—
Total assets	$ 799,829	$ 393,068
Liabilities, Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 6,351	$ 6,991
Accrued expenses and other current liabilities	5,760	3,746
Operating lease liabilities, current	1,521	1,249
Total current liabilities	13,632	11,986
Operating lease liabilities, net of current portion	22,901	23,583
Restricted stock liability	3	156
Total liabilities	36,536	35,725
Commitments and contingencies (Note 13)		
Convertible preferred stock (Series A, B and C), $0.001 par value; no shares authorized as of December 31, 2020 and 337,272,859 shares authorized as of December 31, 2019; no shares issued and outstanding as of December 31, 2020 and 212,642,857 shares issued and outstanding (aggregate liquidation preference of $519,825) as of December 31, 2019	—	537,781
Stockholders' equity (deficit):		
Undesignated preferred stock, $0.001 par value, 10,000,000 shares authorized as of December 31, 2020 and no shares authorized as of December 31, 2019; no shares issued and outstanding at December 31, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value; 150,000,000 and 260,000,000 shares authorized at December 31, 2020 and December 31, 2019, respectively; 89,991,324 and 4,716,634 shares issued at December 31, 2020 and December 31, 2019, respectively; 89,906,835 and 4,037,476 shares outstanding at December 31, 2020 and December 31, 2019, respectively	90	4
Additional paid-in capital	1,167,367	8,715
Accumulated other comprehensive income	64	325
Accumulated deficit	(404,228)	(189,482)
Total stockholders' equity (deficit)	763,293	(180,438)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 799,829	$ 393,068

See accompanying notes.

Relay Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Year Ended December 31,	
	2020	2019
Revenue:		
License revenue	$ 82,654	$ —
Total revenue	82,654	—
Operating expenses:		
Research and development expenses	99,862	70,306
General and administrative expenses	38,588	13,742
Total operating expenses	138,450	84,048
Loss from operations	(55,796)	(84,048)
Other income (expense):		
Interest income	3,400	8,801
Other expense	(16)	(58)
Total other income (expense), net	3,384	8,743
Net loss	$ (52,412)	$ (75,305)
Deemed dividend resulting from extinguishment upon modification of Series C preferred stock	(177,789)	—
Net loss attributable to common stockholders	$ (230,201)	$ (75,305)
Net loss attributable to common stockholders per share, basic and diluted	$ (5.40)	$ (21.82)
Weighted average shares of common stock, basic and diluted	42,619,582	3,450,500
Other comprehensive income (loss):		
Unrealized holding gain (loss)	(261)	325
Total other comprehensive income (loss)	(261)	325
Total comprehensive loss	$ (52,673)	$ (74,980)

See accompanying notes.

Relay Therapeutics, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Additional	Accumulated Other		Total Stockholders'
	Shares	Amount	Shares	Par value	Paid-in Capital	Comprehensive Income	Accumulated Deficit	Equity (Deficit)
Balances at December 31, 2018	210,863,764	$ 532,120	2,998,017	$ 3	$ 3,247	$ —	$ (114,177)	$ (110,927)
Issuance of Series C convertible preferred stock, net of issuance costs of $50	1,779,093	5,661	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	178,969	—	613	—	—	613
Vesting of restricted common stock	—	—	860,490	1	399	—	—	400
Stock-based compensation expense	—	—	—	—	4,456	—	—	4,456
Unrealized gain on investments	—	—	—	—	—	325	—	325
Net loss	—	—	—	—	—	—	(75,305)	(75,305)
Balances at December 31, 2019	212,642,857	537,781	4,037,476	4	8,715	325	(189,482)	(180,438)
Extinguishment upon modification of Series C preferred stock	—	177,789	—	—	(15,455)	—	(162,334)	(177,789)
Conversion of convertible preferred stock into common stock upon initial public offering	(212,642,857)	(715,570)	61,992,534	62	715,508	—	—	715,570
Issuance of common stock in public offering, net of discounts and issuance costs of $34,707	—	—	23,000,000	23	425,270	—	—	425,293
Issuance of common stock upon exercise of stock options	—	—	297,000	—	1,216	—	—	1,216
Vesting of restricted common stock	—	—	579,825	1	153	—	—	154
Stock-based compensation expense	—	—	—	—	31,960	—	—	31,960
Unrealized loss on investments	—	—	—	—	—	(261)	—	(261)
Net loss	—	—	—	—	—	—	(52,412)	(52,412)
Balances at December 31, 2020	—	$ —	89,906,835	$ 90	$ 1,167,367	$ 64	$ (404,228)	$ 763,293

See accompanying notes.

Relay Therapeutics, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (52,412)	$ (75,305)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	31,960	4,456
Depreciation expense	3,549	2,845
Net amortization of premiums and discounts on investments	(416)	(2,495)
Loss on sale of equipment	—	56
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(4,665)	(2,123)
Lease assets and liabilities, net	571	1,233
Accounts payable	(410)	3,000
Accrued expenses and other liabilities	2,010	2,200
Accounts receivable	(75,000)	—
Contract asset	(7,654)	—
Other assets	(22)	—
Net cash used in operating activities	(102,489)	(66,133)
Cash flows from investing activities:		
Purchases of property and equipment	(1,931)	(8,002)
Proceeds from sale of equipment	—	20
Purchases of investments	(266,455)	(553,517)
Proceeds from maturities of investments	350,058	242,475
Net cash provided by (used in) investing activities	81,672	(319,024)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	4,993
Proceeds from issuance of common stock upon exercise of stock options	1,216	613
Proceeds from issuance of common stock upon initial public offering	427,800	—
Offering costs paid	(2,507)	—
Net cash provided by financing activities	426,509	5,606
Net increase (decrease) in cash, cash equivalents and restricted cash	405,692	(379,551)
Cash, cash equivalents and restricted cash at beginning of period	42,832	422,383
Cash, cash equivalents and restricted cash at end of period	$ 448,524	$ 42,832
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment additions included in accounts payable and accrued expenses	$ 519	$ 745
Reclassification of restricted stock liability to additional paid-in capital	$ 153	$ 400
Extinguishment upon modification of Series C preferred stock	$ (177,789)	$ —
Conversion of preferred stock into common stock upon initial public offering	$ 715,508	—
Right of use asset obtained in exchange for lease obligation	$ 819	$ 24,936

Reconciliation of Cash, Cash Equivalents and Restricted Cash from Balance Sheets to Statements of Cash Flows

	Year Ended December 31,	
	2020	2019
Cash and cash equivalents	$ 447,646	$ 41,954
Restricted cash	878	878
Total cash, cash equivalents and restricted cash as shown on consolidated statements of cash flows	$ 448,524	$ 42,832

See accompanying notes.

1. Nature of Business and Basis of Presentation

Relay Therapeutics, Inc. (the "Company") was incorporated in Delaware on May 4, 2015 and is headquartered in Cambridge, Massachusetts. The Company is a clinical-stage, precision medicines company transforming the drug discovery process with an initial focus on enhancing small molecule therapeutic discovery in targeted oncology. The Company is built upon unparalleled insights into protein motion and how this dynamic behavior relates to protein function. The Company's Dynamo platform integrates an array of leading edge experimental and computational approaches, which allows the Company to apply the understanding of protein structure and motion to drug discovery. The Company is advancing its pipeline of medicines to address targets in precision oncology, including its lead product candidates, RLY-4008 and RLY-1971, as well as its PI3Kα mutant selective program, known as the RLY-PI3K1047 program. The Company initiated a Phase 1 clinical trial for RLY-1971 in patients with advanced solid tumors in the first quarter of 2020 and a first-in-human clinical trial of RLY-4008 enriched for patients with advanced solid tumors having oncogenic FGFR2 alterations in the third quarter of 2020. In December 2020, the Company entered into the Collaboration and License Agreement (the "Genentech Agreement") with Genentech, Inc. ("Genentech"), a member of the Roche Group, for the development and commercialization of RLY-1971, as further discussed in Note 5.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities.

The Company's product candidates are in development. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

The Company has devoted substantially all of its resources to developing its product candidates, including RLY-1971 and RLY-4008, and the RLY-PI3K1047 program by developing its innovative, experimental and computational approaches on protein motion, building its intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations.

The Company has incurred net operating losses since inception and had an accumulated deficit of $404,228 as of December 31, 2020. The Company expects that its existing cash, cash equivalents and investments as of December 31, 2020, together with the upfront payment of $75,000 received in January 2021 from Genentech under the Genentech Agreement discussed in Note 5, will enable it to fund its planned operating expenses and capital expenditure requirements for at least one year from the date of the issuance of these consolidated financial statements. The future viability of the Company is dependent on its ability to generate cash from operating activities or to raise additional capital to finance its operations. The Company's failure to raise capital as and when needed could have a material adverse effect on its financial condition and ability to pursue its business strategies. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into license or collaboration arrangements or obtain government grants. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects. In the event

the Company requires additional funding, there can be no assurance that it will be successful in obtaining sufficient funding on terms acceptable to the Company to fund its continuing operations, if at all.

Initial Public Offering

On July 20, 2020, the Company closed its initial public offering ("IPO") and issued 23,000,000 shares of its common stock at a price of $20.00 per share for net proceeds of $425,293, after deducting underwriting discounts and commissions of $32,200 and expenses of $2,507. In connection with the IPO, all shares of Series A, Series B and Series C convertible preferred stock converted into 61,992,534 shares of common stock.

Reverse Stock Split

On July 8, 2020, the Company's stockholders approved a decrease in the number of authorized shares of common stock from 260,000,000 to 150,000,000. The Company also effected a one-for-3.55092 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's preferred stock. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

2. Significant Accounting Policies

Basis of presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for reporting on Form 10-K. The Company's consolidated financial statements include the accounts of Relay Therapeutics, Inc. and its wholly-owned subsidiary, Relay Therapeutics Securities Corporation. All intercompany balances and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual of research and development and manufacturing expenses, the valuation of equity instruments, the determination of the transaction price and standalone selling price of performance obligations under Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, and the incremental borrowing rate for determining the operating lease assets and liabilities. Estimates are periodically reviewed in light of changes in circumstances, facts and experience.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including expenses, clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international markets. The Company has made estimates of the impact of COVID-19 within its financial statements and there may be changes to those estimates in future periods. Actual results could differ from the Company's estimates.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on using innovative experimental and computational approaches on protein motion for making medicines against intractable precision medicine targets. The Company operates in the United States and all tangible assets are held in the United States.

Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at acquisition date to be cash equivalents. Cash equivalents, which consist of money market funds, are stated at fair value.

Restricted Cash

The Company had restricted cash of $878 as of December 31, 2020 and 2019 to secure a letter of credit in connection with the lease of the Company's facilities (see Note 14). The Company classified the restricted cash as a noncurrent asset on its consolidated balance sheets.

Investments

Investments in marketable securities are classified as available-for-sale. Available-for-sale securities are measured and reported at fair value using quoted prices in active markets for similar securities. Unrealized gains and losses on available-for-sale securities are reported as a separate component of stockholders' equity (deficit). Premiums or discounts from par value are amortized to investment income over the life of the underlying investment. All of the Company's available-for-sale securities are available to the Company for use in current operations. As a result, the Company classified all of these securities as current assets even though the stated maturity of some individual securities may be one year or more beyond the balance sheet date.

The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included in other income (expense) within the consolidated statements of operations and comprehensive loss. If any adjustment is required to reflect a decline in the value of the investment that the Company considers to be "other than temporary", the Company recognizes a charge to the consolidated statement of operations and comprehensive loss. No such adjustments were necessary during the periods presented.

Concentration of Credit Risk and Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and investments. From time to time, the Company has maintained all of its cash, cash equivalents and investments at certain accredited financial institutions in amounts that exceed federally insured limits. The Company generally invests its excess capital in money market funds, U.S. treasury bonds, U.S. treasury bills and agency bonds are subject to minimal credit and market risk. Management has established guidelines relative to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. The investment portfolio is maintained in accordance with the Company's investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer.

The Company is dependent on third-party suppliers for research and development activities of its programs, including preclinical and clinical testing. In particular, the Company relies and expects to continue to rely on a small number of these suppliers, including D. E. Shaw Research, LLC as discussed in Note 13, to meet its requirements for its programs. These programs could be adversely affected by a significant interruption in pre-clinical and clinical testing and the supply of active pharmaceutical ingredients and formulated drugs.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) 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.

Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

Revenue Recognition

The Company accounts for revenue recognition in accordance with Accounting Standards Codification Topic ("ASC") 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 the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity 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 entity 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 the contract and determines those that are performance obligations. The Company then determines the transaction price and allocates it to the performance obligations using the relative selling price model. As part of the accounting for these arrangements, the Company must use significant judgment to determine: (a) the number of performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above, including the determination of whether milestones or other variable consideration should be included in the transaction price; and (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of the transaction price in step (iv) above.

The Company utilizes key assumptions and judgments to determine the stand-alone selling price for each performance obligation, which may include discounted cash flow models, evaluation of comparable transactions, pricing considered in negotiating the transaction and estimated costs, to determine how the transaction price is allocated among the performance obligations. The Company uses judgment to determine whether milestones or other variable consideration should be included in the transaction price. For revenue-based royalties, including milestone payments based on the level of sales, the Company will include royalties in the transaction price at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty is allocated has been satisfied (or partially satisfied). As part of management's evaluation of the transaction price, the Company considers numerous factors, including whether the achievement of the milestones is outside of our control, contingent upon the efforts of others or subject to scientific risks of success. If the Company concludes it is probable that a significant revenue reversal would not occur, the associated milestone payment is included in the transaction price. Milestone payments that are not within our control, such as regulatory approvals, are generally not considered probable until those milestones are achieved. The Company re-evaluates the transaction price, including estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Once the performance obligations are identified, the transaction price is allocated to each performance obligation based on the relative stand-alone selling price. 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, either at a point in time or over time. If the performance obligation is satisfied over time, the Company recognizes revenue based on the use of either an output or input method.

As of December 31, 2020, the Company had one collaboration and license agreement with Genentech, which the Company entered into on December 11, 2020. For a discussion of the accounting related to the Genentech Agreement, see Note 5, *Collaboration and License Arrangement with Genentech.*

Lease Agreements

Under ASC 842, *Leases*, the Company determines if an arrangement is or contains a lease at inception. For leases with a term of 12 months or less, the Company does not recognize a right-of-use asset or lease liability. The Company's operating leases are recognized on its consolidated balance sheets as other noncurrent assets, other current liabilities and other noncurrent liabilities. The Company does not have any finance leases.

Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As the Company's leases typically do not provide an implicit rate, the Company uses an estimate of its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. Operating lease right-of-use assets also include the effect of any lease payments made prior to commencement and excludes lease incentives. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense is recognized on a straight-line basis over the lease term.

The Company has lease agreements with lease and non-lease components, which are accounted for as a combined element.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the useful life of the asset. Laboratory and computer equipment are depreciated over three years. Furniture and fixtures are depreciated over five years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the related asset. Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of Long-Lived Assets

The Company continually evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured in an amount by which the book values of the assets exceed their fair value. The Company did not recognize any impairment losses for the years ended December 31, 2020 and 2019.

Classification and Accretion of Convertible Preferred Stock

The Company's convertible preferred stock was classified outside of stockholders' equity (deficit) on the consolidated balance sheet because the holders of such shares had liquidation rights in the event of a deemed liquidation that, in certain situations, were not solely within the control of the Company and would require the redemption of the then-outstanding convertible preferred stock. The convertible preferred stock was not currently redeemable, except in the event of a deemed liquidation (see Note 8). Because the occurrence of a deemed liquidation event was not probable, the carrying value of the convertible preferred stock was not accreted to their redemption values. Subsequent adjustments to the carrying values of the convertible preferred stock would have been made only when a deemed liquidation event became probable.

Upon the closing of the Company's IPO in July 2020, all outstanding convertible preferred stock automatically converted into 61,992,534 shares of common stock.

Stock-Based Compensation

The Company measures stock options and other stock-based awards granted to employees, directors and non-employees based on their fair value on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company recognizes the impact of forfeitures on stock-based compensation expense as forfeitures occur.

The Company issued certain options with performance-based vesting conditions whereby the service inception date preceded the accounting grant date and therefore applied variable accounting for the awards until the fair value of the awards was known on the accounting grant date. The board of directors approved the commencement of vesting for all such awards in 2020, therefore the Company no longer applies variable accounting as of December 11, 2020.

The Company estimates the fair value of each stock option grant on the date of grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of the Company's common stock and assumptions the Company makes for the volatility of its common stock, the expected term of the stock options, the risk-free interest rate for a period that approximates the expected term of the stock options and the expected dividend yield.

Prior to the Company's IPO, the estimated fair value of its common stock was determined by the board of directors, or compensation committee thereof, as of the date of each option grant, with input from management, considering the most recently available third-party valuations of common stock and the board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. Historically, these independent third-party valuations of the Company's equity instruments were performed contemporaneously with identified value inflection points.

These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the "Practice Aid"). The Practice Aid identifies various available methods for allocating the enterprise value across classes of series of capital stock in determining the fair value of the Company's common stock at each valuation date.

Following the Company's IPO, in connection with the accounting for granted stock options and other awards the Company may grant, the fair value of the Company's common stock is determined based on the quoted market price of its common stock.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses include salaries, stock-based compensation and benefits of employees, third-party license fees and other operational costs related to the Company's research and development activities, including allocated facility-related expenses and external costs of outside vendors engaged to conduct both pre-clinical studies and clinical trials. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Research and Manufacturing Contracts

The Company has entered into various research and development contracts with research institutions and other companies whose costs are included in research and development expense in the accompanying consolidated statements of operations and comprehensive loss. These agreements are generally cancelable and related payments are recorded as research and development expenses as the underlying services are performed. When evaluating the adequacy of the expense recognized, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the expense recognized and the related prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amounts and the tax bases of the assets and liabilities using the enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance against deferred tax assets is recorded if, based on the weight of the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2020 and 2019, other comprehensive income (loss) consisted of changes in unrealized gains and losses from available-for-sale investments.

Net Loss Per Common Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the sum of the weighted average number of common shares outstanding during the period and the effect of dilutive securities.

The Company applies the two-class method to calculate its basic and diluted net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. The Company's participating securities contractually entitle the holders of such shares to participate in dividends; but do not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities.

Additionally, in periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. For additional discussion of net loss per common share, please see Note 12, *Net Loss Per Share.*

Recently Adopted Accounting Pronouncements

The Company adopted Accounting Standards Update ("ASU") No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* on January 1, 2020. This standard modifies certain disclosure requirements on fair value measurements. The adoption of this standard did not have a material impact on the Company's disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. This standard requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and it establishes additional disclosure requirements related to credit risks. For available-for-sale securities with expected credit losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. This guidance was originally effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption was permitted. In November 2019, the FASB subsequently issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates* ("ASU 2019-10"), whereby the effective date of this standard for smaller reporting companies was deferred to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, and early adoption is still permitted. The Company is assessing the impact of ASU 2019-10 on the consolidated financial statements and does not expect it to have a material impact.

In August 2020, the FASB issued ASU No. 2020-06, *Debt – Debt with Conversion and Other Options* (Subtopic 470-20) *and Derivatives and Hedging—Contracts in Entity's Own Equity* (Subtopic 815-40) ("ASU 2020-06"). This standard amends the guidance on convertible instruments and the derivatives scope exception for contracts in an entity's own equity and amends the related earnings per share ("EPS") guidance. The ASU will be effective for smaller reporting companies for fiscal years beginning after December 15, 2023 and interim periods within those fiscal years. Early adoption is permitted in fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company is assessing the impact of ASU 2020-06 on the consolidated financial statements and does not expect it to have a material impact.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends certain aspects of the existing guidance to improve consistent application. The new standard will be effective for public business entities for fiscal years beginning after December 15, 2020. The Company is assessing the potential impact ASU 2019-12 may have on its financial statements upon adoption.

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected to use the extended transition period related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different effective dates for public and nonpublic companies, the Company can adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and can do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company.

3. Fair Value of Financial Assets

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

	Fair Value Measurements as of December 31, 2020:			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	$ 447,146	$ —	$ —	$ 447,146
Investments:				
US treasury bills	—	33,026	—	33,026
US agency securities	—	197,389	—	197,389
Total investments	—	230,415	—	230,415
Total	$ 447,146	$ 230,415	$ —	$ 677,561

	Fair Value Measurements as of December 31, 2019:			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	$ 41,658	$ —	$ —	$ 41,658
Investments:				
US treasury bills	—	232,604	—	232,604
US agency securities	—	81,258	—	81,258
Total investments	—	313,862	—	313,862
Total	$ 41,658	$ 313,862	$ —	$ 355,520

In determining the fair value of its investments at each date presented above, the Company relied on quoted prices for similar securities in active markets or using other inputs that are observable or can be corroborated by observable market data. The Company did not have any financial assets or liabilities during any of the periods presented in the accompanying consolidated financial statements that required Level 3 inputs.

4. Investments

The fair value of available-for-sale investments by type of security was as follows:

	December 31, 2020			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Investments:				
U.S treasury bills	$ 29,997	$ 21	$ —	$ 30,018
U.S agency securities	20,996	5	—	21,001
Total investments with a maturity of one year or less	50,993	26	—	51,019
U.S treasury bills	3,008	—	—	3,008
U.S agency securities	176,350	38	—	176,388
Total investments with a maturity of one to two years	179,358	38	—	179,396
Total investments	$ 230,351	$ 64	$ —	$ 230,415

	December 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Investments:				
U.S treasury bills	$ 232,336	$ 268	$ —	$ 232,604
U.S agency securities	81,201	57	—	81,258
Total investments with a maturity of one year or less	$ 313,537	$ 325	$ —	$ 313,862

5. Collaboration and License Arrangement with Genentech

On December 11, 2020, the Company entered into the Genentech Agreement, which granted Genentech a license to develop and commercialize RLY-1971. RLY-1971 is currently being developed in a Phase 1a clinical trial for patients with advanced solid tumors (the "Phase 1a Trial"). Unless Genentech elects to exercise its option to conduct the remainder of the ongoing Phase 1a Trial, the Company is responsible for the completion of this trial. Genentech is responsible for conducting all subsequent clinical development of RLY-1971. The Company is also responsible for the one-time transfer of the active pharmaceutical ingredient ("API") and other materials related to RLY-1971 to Genentech.

Under the Genentech Agreement, the Company is entitled to a non-refundable upfront payment of $75,000, which is due upon completion of certain technology transfer activities and is reflected as accounts receivable on the consolidated balance sheet at December 31, 2020. The Company collected this amount in full in January 2021. The Company is eligible to receive up to $25,000 in near-term milestone payments. The Company is also eligible to receive up to an aggregate of an additional $695,000 upon the achievement of specified development, commercialization and sales-based milestones for RLY-1971 worldwide as well as tiered royalties ranging from low-to-mid teens on annual worldwide net sales of RLY-1971, on a country-by-country basis, subject to reduction in certain circumstances.

The Company has the option, exercisable one time at the Company's sole discretion, to (a) fund half of the development costs of RLY-1971 in the U.S., (b) share half of the net profits or net loss of commercializing RLY-1971 in the U.S. (the "Profit/Cost Share") and (c) be eligible to receive up to an aggregate of an additional $410,000 upon the achievement of specified commercialization and sales-based milestones for RLY-1971 outside of the U.S and tiered royalties ranging from low-to-mid teens on annual net sales of RLY-1971 outside of the U.S., on a country-by-country basis, subject to reduction in certain circumstances. The Company may elect to opt-out of further participation in the Profit/Cost Share at any time prior to the third anniversary of the first commercial sale of RLY-1971 in the U.S, in which case the financial terms would revert to the terms applicable as if Company had not opted into the Profit/Cost Share as of the effective opt-out date.

Genentech may terminate the Genentech Agreement for convenience and the Company may terminate the Genentech Agreement under certain limited circumstances. Unless otherwise terminated, the Genentech Agreement will remain in effect until the expiration of all Genentech's royalty payment obligations to the Company.

Accounting Analysis

Identification of the Contract

The Company concluded that Genentech is a customer in this arrangement and as such, the arrangement falls within the scope of the revenue recognition guidance in ASC 606.

Identification of Performance Obligations

At the commencement of the Genentech Agreement, the Company identified the following performance obligations in the agreement:

- License to develop and commercialize RLY-1971 and the related know-how;
- Research and development services to complete the Phase 1a Trial for RLY-1971; and
- Transfer of API and other materials related to RLY-1971

The Company determined that the performance obligations outlined above are both capable of being distinct and distinct within the context of the contract given such rights and activities are independent of each other. The license can be used by Genentech without the research and development services or API outlined above, and similarly those services and inventory provide distinct benefit to Genentech within the context of the contract, separate from the license.

Determination of Transaction Price

The Company determined the transaction price for the Genentech Agreement to be $85,867, which includes both fixed and variable consideration amounts. The total transaction price of $85,867 is comprised of (i) the $75,000 fixed, non-refundable upfront payment, (ii) a $5,000 non-refundable milestone payment due upon the transfer of the Investigational New Drug ("IND") application to Genentech, (iii) a $5,000 non-refundable milestone payment due upon completion of the Phase 1a Trial for RLY-1971 and (iv) $867 of estimated variable consideration related to reimbursements due from Genentech for research and development services. No additional development milestone payments and no regulatory milestone payments are included in the transaction price as all such payments are fully constrained. As part of management's evaluation of the constraint, the Company considered numerous factors, including the consideration that achievement of the milestones is outside of the Company's control, contingent upon Genentech's efforts and the receipt of regulatory approval and subject to scientific risks of success.

Allocation of Transaction Price to Performance Obligations

The Company allocated the transaction price of $85,867 based on the stand-alone selling prices ("SSP") of each of the performance obligations as follows:

- $82,654 million for the transfer of the license
- $2,896 million for research and development services; and
- $317 million for the transfer of API.

The SSP for the license was determined using an approach that considered discounted, probability-weighted cash flows related to the license transferred. The Company also reviewed comparable market transactions in determining the SSP of the license. The SSP for the research and development services as well as the transfer of API were based on estimates of the associated effort and cost of these services and cost to manufacture API, adjusted for a reasonable profit margin that would be expected to be realized under similar contracts. The Company performed sensitivity analyses supporting reasonable changes to the SSPs noting no material impact on revenue recognized for the year ended December 31, 2020.

Recognition of Revenue

The Company is recognizing revenue for each of the three performance obligations as follows:

- The Company recognized revenue related to the license at a point in time upon transfer of the license to Genentech. The Company recognized the full amount allocated to the license and related know-how in the fourth quarter of 2020 because the Company had transferred the license upon execution of the Genentech Agreement. Revenue recognized during the year ended December 31, 2020 related to the license amounted to $82,654.
- The Company will satisfy the research and development performance obligation for RLY-1971 as the research and development services are performed. The research and development services performance obligation consists of the Company completing the Phase 1a clinical trial initiated in the first quarter of 2020. The Company recognizes revenue related to the research and development services over time using a cost-based input method by calculating actual costs incurred to date at each period end relative to total

estimated costs expected to be incurred to fulfill the performance obligation. There was no revenue recognized related to this performance obligation during the year ended December 31, 2020 as the services performed from contract inception to December 31, 2020 were immaterial.

- The Company will recognize revenue related to the transfer of API at a point in time upon transfer to Genentech. There was no revenue recognized related to this performance obligation during the year ended December 31, 2020.

During the year ended December 31, 2020, the Company recognized an aggregate of $82,654 of revenue from the Genentech Agreement related entirely to the transfer of the license. At December 31, 2020, the Company recorded accounts receivable under the Genentech Agreement in the amount of $75,000 and a contract asset in the amount of $7,654, which is classified as a current asset, on the balance sheet. The contract asset relates to the amount of revenue recognized for which the right to payment is contingent upon conditions other than the passage of time, such as the completion of future milestone activities.

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2020	2019
Property and equipment:		
Laboratory equipment	$ 13,534	$ 12,003
Leasehold improvements	886	860
Computer equipment	888	827
Furniture and fixtures	895	895
Construction in process	577	490
	16,780	15,075
Less: accumulated depreciation	(10,530)	(6,981)
Total property and equipment, net	$ 6,250	$ 8,094

The Company recorded $3,549 and $2,845 of depreciation expense for the years ended December 31, 2020 and 2019, respectively.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2020	2019
External research and development	$ 5,099	$ 3,077
Professional services	464	336
Other	197	333
Total accrued expenses and other current liabilities	$ 5,760	$ 3,746

8. Convertible Preferred Stock

The Company issued Series A, Series B and Series C convertible preferred stock (collectively, “Convertible Preferred Stock”). Upon issuance of each class of Convertible Preferred Stock, the Company assessed the embedded conversion and liquidity features of the shares and determined that such features did not require the Company to separately account for these features. The Company also concluded that no beneficial conversion feature existed on the issuance date of each class of Convertible Preferred Stock. The Company’s Convertible Preferred Stock was

classified outside of stockholders' equity (deficit) on the consolidated balance sheet prior to the Company's IPO because the holders of such shares had liquidation rights in the event of a deemed liquidation that, in certain situations, were not solely within the control of the Company and would require the redemption of the then-outstanding Convertible Preferred Stock. The Convertible Preferred Stock was not currently redeemable. Because the occurrence of a deemed liquidation event was not probable, the carrying values of the Convertible Preferred Stock were not accreted to their redemption values.

On July 8, 2020, the Company's board of directors and its Series C preferred stockholders approved a reduction in the conversion price of the Series C preferred stock from $3.21 to $3.027603 and the Series C preferred stockholders relinquished their protective right with respect to the approval of an automatic conversion of preferred stock in a firm commitment underwritten public offering if the per share price is less than $22.80. As a result of the change in the conversion price, the outstanding shares of Series C preferred stock were convertible into 37,206,604 shares of common stock. The changes to the conversion feature were considered to be a significant change to the substantive contractual terms of the Series C preferred stock and, therefore, the Company accounted for the changes as an extinguishment and reissuance of the Series C preferred stock, which required the difference between the fair value of the modified Series C preferred stock and its carrying amount to be treated in a manner similar to the treatment of dividends paid on preferred stock.

Upon the closing of the Company's IPO in July 2020, all outstanding Convertible Preferred Stock automatically converted into 61,992,534 shares of common stock. No Convertible Preferred Stock was outstanding as of December 31, 2020.

Prior to January 1, 2019, the Company issued a total of 56,824,740 shares of Series A convertible preferred stock ("Series A preferred stock"), 31,188,115 shares of Series B convertible preferred stock ("Series B preferred stock") and 122,850,909 shares of Series C convertible preferred stock ("Series C preferred stock") in exchange for net proceeds of $56,692, $62,876 and $393,587, respectively.

During the year ended December 31, 2019, the Company issued an additional 1,779,093 shares of Series C preferred stock at a per share price of $3.21 for proceeds of $5,661, net of issuance costs.

Convertible Preferred Stock consisted of the following:

	December 31, 2019				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A preferred stock	56,824,740	56,824,740	$ 75,657	$ 56,825	16,002,820
Series B preferred stock	31,188,115	31,188,115	62,876	63,000	8,783,102
Series C preferred stock	249,260,004	124,630,002	399,248	400,000	35,097,955
Total convertible preferred stock	337,272,859	212,642,857	$ 537,781	$ 519,825	59,883,877

There were no shares of Convertible Preferred Stock outstanding at December 31, 2020.

The holders of the Convertible Preferred Stock had the following rights and preferences:

Voting

The holders of the Convertible Preferred Stock had voting rights equivalent to the number of shares of common stock into which their shares of preferred stock would convert. So long as any of the Convertible Preferred Stock was outstanding, a requisite vote of the Convertible Preferred Stockholders, which was defined as a majority of the Convertible Preferred Stockholders, was required to affirm certain corporate actions, which included, but was not

limited to, the disposal of assets, the acquisition of assets or a business and the authorization of additional shares of the Company's capital. In addition, such actions required a requisite vote of the Series C preferred stockholders and a majority vote of the Series B preferred stockholders, if any of the respective preferred stock was outstanding.

Dividends

The holders of the Convertible Preferred Stock were entitled to receive noncumulative dividends when and if declared by the Company's board of directors. If the Company declared, paid or set aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Company, the holders of the Convertible Preferred Stock were entitled to the same dividend based on the number of common shares the Convertible Preferred Stock would convert into. No dividends were declared or paid during the years ended December 31, 2020 or 2019.

Liquidation Rights

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the corporation, holders of the Series C preferred stock then outstanding were entitled to be paid out of the assets of the Company available for distribution to its stockholders before any payment was made to the holders of Series A and B preferred stock or common stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the Series C preferred stock original issue price ($3.21), plus any accrued but unpaid dividends declared, and (ii) an amount per share if the Series C preferred stock had been converted prior to the liquidation event.

Next, the holders of the Series A preferred stock then outstanding together with holders of Series B preferred stock were entitled to be paid out of the assets of the Company available for distribution to its stockholders before any payment would be made to the common stockholders by reason of their ownership thereof, an amount per share equal to the greater of (i) their original issue price, which was $1.00 and $2.02 for Series A and B preferred stock, respectively, plus any accrued but unpaid dividends declared, and (ii) an amount per share if the Series A and B preferred stock, respectively, had been converted prior to the liquidation event.

Conversion

The Convertible Preferred Stock was convertible into common stock at any time at the option of the holder, and was subject to automatic conversion upon the closing of a firm commitment underwritten public offering with either a price per share of at least $22.80 and proceeds of at least $100,000 or approval by a specified vote of the Convertible Preferred Stockholders. As of December 31, 2019, the Convertible Preferred Stock was convertible into 59,382,845 shares of common stock.

On July 8, 2020, the required Convertible Preferred Stockholders authorized the automatic conversion of all shares of Convertible Preferred Stock in an IPO, regardless of the price per share or total proceeds raised, as long as the IPO was completed on or before September 30, 2020.

Protective Rights

For as long as any of the Series C preferred stock was outstanding, a requisite vote of the Convertible Preferred Stockholders was required to affirm a liquidation, dissolution, a merger or consolidation or any other deemed liquidation event if the per share proceeds to the holders of the Series C preferred stock would be equal to or greater than $22.80 per share. In addition, both a requisite vote of the Convertible Preferred Stockholders and a majority of the Series C preferred stockholders was required to affirm a liquidation, dissolution, a merger or consolidation or any other deemed liquidation event if the per share proceeds to the holders of the Series C preferred stock was less than $22.80 per share.

9. Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company's board of directors, however, holders of convertible preferred stock were entitled to any dividend received by the common

stockholders if each preferred share had been converted into common stock. As of December 31, 2020 and 2019, no dividends had been declared.

The Company issued restricted shares of common stock to its founders and non-employees. In addition, the Company issued restricted shares of common stock upon the early exercise of stock options under the Company's 2016 Stock Option and Grant Plan (the "2016 Stock Plan"). The restrictions on the common shares generally lapse over four years. The Company included the proceeds from the sale of the restricted shares of common stock as a restricted stock liability on the accompanying consolidated balance sheets. Amounts are reclassified to additional paid-in capital as the restrictions lapse. The Company has the right to repurchase any unvested shares of restricted common stock at the original cost in the event of termination.

The following table summarizes the restricted stock activity for the year ended December 31, 2020:

	Shares	Weighted-Average Purchase Price
Unvested at December 31, 2019	679,158	$ 0.21
Vested	(579,825)	0.26
Cancelled	(14,844)	0.03
Unvested at December 31, 2020	84,489	0.04

The fair value of shares that vested during the year ended December 31, 2020 was $9,619.

The Company has reserved the following shares of common stock:

	December 31,	
	2020	2019
Conversion of Series A preferred stock	—	16,002,820
Conversion of Series B preferred stock	—	8,783,102
Conversion of Series C preferred stock	—	35,097,955
Shares reserved under the compensation plan	8,026,772	8,407,169
Total shares of common stock reserved for issuance	8,026,772	68,291,046

Employee Stock Purchase Plan

On July 8, 2020, the Company's stockholders approved the 2020 Employee Stock Purchase Plan (the "ESPP"). The ESPP became effective on the date immediately prior to the effectiveness of Company's registration statement on Form S-1 for its IPO. As of December 31, 2020, the ESPP provides for the issuance of up to 1,092,532 of share-based awards. As of December 31, 2020, no shares have been issued under the ESPP.

10. Share-Based Payments

In 2016, the Company adopted the 2016 Stock Plan. On July 8, 2020, the Company's stockholders approved the 2020 Stock Option and Incentive Plan (the "2020 Stock Plan"), which became effective on the date immediately prior to the effectiveness of the Company's registration statement on Form S-1 for its IPO. The 2020 Stock Plan provides for the issuance of up to 8,376,080 of share-based awards. Subsequent to July 20, 2020, no further awards will be made under the 2016 Stock Plan and all future equity-based awards will be granted under the 2020 Stock Plan. To the extent outstanding options granted under the 2016 Plan are cancelled, forfeited or otherwise terminated without being exercised and would otherwise have been returned to the share reserve under the 2016 Plan, the number of shares underlying such awards will be available for future grant under the 2020 Stock Plan. All of the Company's employees, officers, directors and consultants are eligible to be granted options, restricted stock units

and other stock-based awards under the terms of the 2020 Stock Plan. There were 8,026,772 share-based awards available for grant at December 31, 2020.

The following table summarizes the stock option activity under the 2016 Stock Plan and the 2020 Stock Plan for the year ended December 31, 2020:

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	5,306,176	$ 4.62	8.99	$ 3,214
Granted	2,898,663	10.90		
Exercised	(297,000)	4.09		
Cancelled	(210,781)	4.91		
Outstanding at December 31, 2020	7,697,058	$ 6.99	8.50	$ 266,050
Vested at December 31, 2020	2,148,119	$ 4.49	7.90	$ 79,625
Non-vested at December 31, 2020	5,548,939	$ 7.96	8.74	$ 186,425

In the first quarter of 2020, the Company's board of directors approved the issuance of options with performance-based vesting conditions to purchase 1,960,547 shares of common stock. The commencement of vesting was based on the achievement of certain scientific and operational milestones during a two-year period, for which the achievement was discretionary and subject to the approval of the Company's board of directors. Accordingly, the Company applied variable accounting for these awards until the board of directors approved the commencement of vesting for the options. The service inception date preceded the grant date for these awards as the awards were authorized prior to the grant date, the recipients were providing service prior to the grant date and there were performance conditions that, if not met by the accounting grant date, would have resulted in the forfeiture of the award. The stock-based compensation expense for the options was determined based on the fair value of the awards on the accounting grant date. The Company's board of directors, in its discretion, determined that a portion of the performance conditions were achieved during the second quarter of 2020 and that the remaining portion of the performance conditions were achieved during the fourth quarter of 2020. The grant dates for all performance-based awards was therefore known as of December 31, 2020, and all performance conditions have been resolved. The Company recognized stock-based compensation expense associated with the awards with performance-based vesting conditions in the amount of $25,527 in the statement of operations for the year ended December 31, 2020. Expense for these awards is recognized using an accelerated attribution model, over the four-year vesting term, commencing upon grant date.

The Company estimated the fair value of its stock options using the following assumptions:

	Year Ended December 31,	
	2020	2019
Risk-free interest rate	0.4 - 1.8%	1.5 – 2.5%
Expected term (in years)	6.3	6.3
Expected volatility	73.5 - 77.6%	72.8 – 73.47%
Expected dividend yield	0%	0%

The weighted average grant date fair value of stock options granted during the years ended December 31, 2020 and 2019 was $30.14 per share and $3.34 per share, respectively.

Stock-based compensation expense included in the Company's consolidated statements of operations and comprehensive loss is as follows:

	Year Ended December 31,	
	2020	2019
Research and development expenses	$ 14,691	$ 2,687
General and administrative expenses	17,269	1,769
	$ 31,960	$ 4,456

As of December 31, 2020, total unrecognized compensation cost related to the unvested stock-based awards was $69,948, which is expected to be recognized over a weighted average period of 2.61 years.

11. Income Taxes

During the years ended December 31, 2020 and 2019, the Company recorded no income tax benefits due to the losses incurred due to the uncertainty of future taxable income.

A reconciliation of the expected income tax (benefit) computed using the federal statutory income tax rate to the Company's effective income tax rate is as follows for the year ended December 31, 2020 and 2019:

	December 31,	
	2020	2019
Income tax computed at federal statutory rate	21%	21.0%
State taxes, net of federal benefit	5.7%	7.0%
Change in valuation allowance	(27.3)%	(31.0)%
R&D credit carryovers	7.6%	4.1%
Stock-based compensation	(6.7)%	(0.9)%
Permanent differences	(0.3)%	(0.2)%
Total	0.0%	0.0%

The Company's deferred tax assets at December 31, 2020 and 2019, consist of the following:

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating losses	$ 48,832	$ 42,647
Tax credit carryforwards	10,270	6,309
Lease liability	6,430	6,542
Intangibles	1,469	1,498
Stock-based compensation	4,496	534
Depreciation and amortization	230	188
Other	14	13
Total gross deferred tax asset	71,741	57,731
Valuation allowance	(65,813)	(51,537)
Net deferred tax asset	5,928	6,194
Deferred tax liability		
Operating lease assets	(5,928)	(6,194)
Total deferred tax liability	(5,928)	(6,194)
	$ —	$ —

The Company has incurred net operating losses ("NOL") since inception. As of December 31, 2020, the Company had federal NOL carryforwards of $174,028 available to reduce taxable income, of which $43,127 expire beginning

in 2035 and $130,901 do not expire. The Company has state NOL carryforwards of $192,346 as of December 31, 2020 available to reduce future state taxable income, which expire at various dates beginning in 2035.

As of December 31, 2020, the Company also had available federal research and development tax credit carryforwards of $8,139 available to reduce future tax liabilities, which begin to expire beginning in 2035. The Company also has state research and development tax credit carryforwards of $2,699 available to reduce future state tax liabilities, which expire at various dates beginning in 2030.

Utilization of the NOL carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 (“Section 382”) due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company’s stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company recorded a valuation allowance against its deferred tax assets for the years ended December 31, 2020 and 2019 because the Company’s management believes that it is more likely than not that these assets will not be realized. The valuation allowance increased by approximately $14,276 and $23,307 for the years ended December 31, 2020 and 2019, respectively, primarily as a result of operating losses generated with no corresponding financial statement benefit.

The Company had no unrecognized tax benefits as of December 31, 2020 and 2019.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company’s tax years are still open under statute from inception to the present.

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act (CARES Act) was signed into law in March 2020. The CARES Act lifts certain deduction limitations originally imposed by the Tax Cuts and Jobs Act of 2017 (“2017 Tax Act”). Corporate taxpayers may carryback NOLs originating during 2018 through 2020 for up to five years, which was not previously allowed under the 2017 Tax Act. The CARES Act also eliminates the 80% of taxable income limitations by allowing corporate entities to fully utilize NOL carryforwards to offset taxable income in 2018, 2019 or 2020. Taxpayers may generally deduct interest up to the sum of 50% of adjusted taxable income plus business interest income (30% limit under the 2017 Tax Act) for tax years beginning January 1, 2019 and 2020. The CARES Act allows taxpayers with alternative minimum tax credits to claim a refund in 2020 for the entire amount of the credits instead of recovering the credits through refunds over a period of years, as originally enacted by the 2017 Tax Act.

In addition, the CARES Act raises the corporate charitable deduction limit to 25% of taxable income and makes qualified improvement property generally eligible for 15-year cost-recovery and 100% bonus depreciation. The enactment of the CARES Act did not result in any adjustments to the Company’s income tax provision for the year ended December 31, 2020, or to the Company’s net deferred tax assets as of December 31, 2020, since the Company has not recorded any U.S. federal or state income tax benefits for the net losses incurred in any year due to the uncertainty of realizing a benefit from those items.

12. Net Loss Per Share

The following table summarizes the computation of basic and diluted net loss per share of the Company:

	Year Ended December 31,	
	2020	2019
Net loss	$ (52,412)	$ (75,305)
Deemed dividend resulting from extinguishment upon modification of Series C preferred stock	(177,789)	—
Net loss attributable to common stockholders	$ (230,201)	$ (75,305)
Net loss attributable to common stockholders per share, basic and diluted	$ (5.40)	$ (21.82)
Weighted average shares of common stock, basic and diluted	42,619,582	3,450,500

As discussed in Note 8, on July 8, 2020, the Company's board of directors and its Series C preferred stockholders approved an amendment to the conversion preferences and rights of the Series C preferred stock which, among other changes, resulted in a reduction in the conversion price of the Series C preferred stock from $3.21 to $3.027603. The changes to the conversion feature were considered to be a significant change to the substantive contractual terms of the Series C preferred stock and, therefore, the Company accounted for the changes as an extinguishment and reissuance of the Series C preferred stock. In accordance with SEC staff guidance codified in ASC 260-10-S99-2, when equity classified preferred shares are extinguished, the difference between (1) the fair value of the consideration transferred to the holders of the preferred shares and (2) the carrying amount of the preferred shares, net of issuance costs, is subtracted from (or added back to) net income to arrive at income available to common stockholders in the calculation of earnings per share. This difference between the fair value of consideration transferred and carrying amount of the preferred shares, also referred to as a "deemed dividend", was therefore added back to net loss above to derive net loss attributable to common stockholders.

The Company's potentially dilutive securities, which include Convertible Preferred Stock (prior to the IPO), options to purchase common stock and unvested restricted stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2020	2019
Convertible preferred stock	—	59,883,877
Options to purchase common stock	7,697,058	5,306,176
Unvested restricted stock	84,489	679,158
	7,781,547	65,869,211

13. Commitments and Contingencies

Intellectual Property License

The Company has a Collaboration and License Agreement with D. E. Shaw Research, LLC ("D. E. Shaw Research"), which held 9,999,999 shares of Series A preferred stock and 1,557,875 shares of Series C preferred stock at December 31, 2019. Upon the IPO these shares were converted into 3,281,253 shares of common stock, which are outstanding at December 31, 2020. The agreement provides that the parties will jointly conduct research efforts with the goal of identifying and developing product candidates. The original term of the agreement was three years and required the Company to pay an annual fee of $1,000. On June 15, 2020, the Company and D. E. Shaw Research agreed to amend the Collaboration and License Agreement (the "Amended and Restated Collaboration and

License Agreement"). The Amended and Restated Collaboration and License Agreement extended the term of the agreement to August 16, 2025 and increased the annual fee from $1,000 to $7,900. The Amended and Restated Collaboration and License Agreement automatically renews for successive one year periods unless either party provides at least one year notice of non-renewal, and the annual fee during each of the one year renewal terms is subject to the mutual agreement of the Company and D. E. Shaw Research.

The Company is obligated to pay potential development milestone payments under the terms of the agreement up to $7,300 per target, plus sales milestones and royalties, upon the achievement of certain specified contingent events. Such payments for achievement of development and regulatory milestones total up to $7,250 in the aggregate for each of the first three products the Company develops, and up to $6,250 in the aggregate for each product the Company develops after the first three. The Company assessed the milestone and royalty events through December 31, 2020 and concluded $1,500 was due to D.E. Shaw related to the execution of the Genentech Agreement in December 2020. The Company concluded no such payments were due as of December 31, 2019. The Company recorded research and development expense of $6,376 and $1,500 under this agreement for the years ended December 31, 2020 and 2019, respectively. At December 31, 2020 and December 31, 2019, the Company had an accrued expense balance to D. E. Shaw Research of approximately $1,500 and $372, respectively, on its balance sheets.

Other Research Arrangements

The Company has certain other research and license arrangements with third-parties, which provide the Company with research services with the goal of identifying and developing product candidates. The Company is obligated to pay development milestone payments for up to four targets, each in the range of $4,000 to $7,000 upon the achievement of certain specified contingent events. The Company assessed the milestones at December 31, 2020 and 2019 and concluded no such milestone payments were due. The Company incurred approximately $2,704 and $3,493 of research and development expense under these agreements in the years ended December 31, 2020 and 2019, respectively.

14. Leases

215 First Street

The Company leased office and laboratory space at 215 First Street in Cambridge, Massachusetts ("First Lease") under an operating lease, which commenced in November 2015 and was originally set to expire in December 2020. As discussed below, the Company executed a lease at 399 Binney Street ("Binney Lease") whereby the Company vacated the 215 First Street lease in January 2019 and the future lease commitments terminated at no cost once the Binney Lease commenced. The lease included certain tenant improvement allowances, which the Company amortized through January 2019, the termination of the lease.

399 Binney Street

In December 2017, the Company entered into a facility lease agreement for approximately 44,336 square feet of office and laboratory space at 399 Binney Street, Cambridge, Massachusetts, which was increased to 44,807 square feet in January 2018. The Company gained control of the leased space in January 2019 and recorded a right of use asset and a lease liability, accordingly. The lease expires in April 2029, subject to certain renewal options, which have not been included in the Company's right of use asset and liability, as the Company is not reasonably certain to exercise those options.

In September 2020, the Company entered into an amendment to its facility lease agreement to expand the leased area by approximately 1,824 square feet of office space at 399 Binney Street, Cambridge, Massachusetts. The amended lease expires in April 2029, subject to certain renewal options. The amendment to the lease agreement met the criteria to be accounted for as a separate lease. The Company gained control of the leased space in October 2020 and recorded a right of use asset and a lease liability, accordingly. The right of use asset and lease liability recorded in connection with this amendment were not material.

As discussed in Note 2, the Company provided a letter of credit in the amount of $878 with a financial institution, which expires September 30, 2028.

The following table summarizes the presentation of the Company's operating leases on its consolidated balance sheets:

	Balance sheet location	December 31, 2020	December 31, 2019
Assets:			
Operating lease assets	Operating lease assets	$ 22,579	$ 23,560
Liabilities:			
Current operating lease liabilities	Operating lease liabilities	$ 1,521	$ 1,249
Non-current operating lease liabilities	Operating lease liabilities, net of current portion	22,901	23,583
	Total lease liabilities	$ 24,422	$ 24,832

The following table summarizes the effect of lease costs in the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2020 and 2019:

	Statement of operations location	Year Ended December 31, 2020	Year Ended December 31, 2019
Operating lease costs	Research and development	$ 3,273	$ 3,216
	General and administrative	748	581
	Total operating lease cost	$ 4,021	$ 3,797

The Company made cash payments of $4,878 and $2,602 under the lease agreements during the years ended December 31, 2020 and 2019, respectively.

The minimum lease payments as of December 31, 2020 for the next five years and thereafter is expected to be as follows:

Year Ending December 31,	Amount
2021	$ 3,985
2022	4,134
2023	4,254
2024	4,377
2025	4,503
Thereafter	15,959
Total lease payments	37,212
Less: interest	(12,790)
Present value of operating lease liabilities	$ 24,422

The weighted average remaining lease term and weighted average discount rate of the operating leases were 8.3 years and 10.4%, respectively, at December 31, 2020. The weighted average remaining lease term and weighted average discount rate of the operating leases were 9.3 years and 10.4%, respectively, at December 31, 2019.

15. Employee Benefits

In 2016, the Company established a defined-contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company made

matching contributions to the 401(k) Plan of $590 for the year ended December 31, 2020. The Company was not required to make and did not make any matching contributions to the 401(k) Plan for the year ended December 31, 2019.

16. Related Party Transactions

From inception to December 31, 2020, the Company received consulting and management services from Third Rock Ventures LLP ("TRV"), an entity affiliated with certain of the Company's investors. The Company did not incur expenses for such services during the year ended December 31, 2020. The Company incurred approximately $200 for these services during the year ended December 31, 2019. No amounts were due to TRV at December 31, 2020. At December 31, 2019, $80 was due to TRV for these services.

17. Subsequent Events

In preparing the consolidated financial statements as of December 31, 2020, the Company evaluated subsequent events for recognition and measurement purposes through the filing date of this Annual Report on Form 10-K. The Company concluded that no events or transactions have occurred that require disclosure in the accompanying consolidated financial statements.

EXHIBIT INDEX

Exhibit Number	Description
3.1	Fourth Amended and Restated Certificate of Incorporation of Relay Therapeutics, Inc. (Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K (File No. 001-39385) filed on July 21, 2020).
3.2	Amended and Restated Bylaws of Relay Therapeutics, Inc. (Incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K (File No. 001-39385) filed on July 21, 2020).
4.1	Specimen stock certificate evidencing the shares of common stock (Incorporated by reference to Exhibit 4.1 to our Registration Statement on Form S-1/A (File No. 333-239412) filed on July 9, 2020).
4.2	Second Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, effective as of December 19, 2018 as amended on June 26, 2020 (incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-239412) filed on July 9, 2020).
4.3*	Description of Securities
10.1#	2016 Stock Option and Grant Plan, and form of award agreements thereunder (incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-239412) filed on June 24, 2020).
10.2#	2020 Stock Option and Incentive Plan, and form of award agreements thereunder (incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239412) filed on July 9, 2020).
10.3#	2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239412) filed on July 9, 2020).
10.4#	Senior Executive Cash Bonus Plan (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-239412) filed on June 24, 2020).
10.5#	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239412) filed on July 9, 2020).
10.6#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-239412) filed on June 24, 2020).
10.7#	Form of Amended and Restated Employment Agreement (incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239412) filed on July 9, 2020).
10.8#	Amended and Restated Employment Agreement, by and between the Registrant and Sanjiv K. Patel dated March 25, 2020 (incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (File No. 333-239412) filed on June 24, 2020).
10.9†	Amended and Restated Collaboration and License Agreement, by and between the Registrant and D. E. Shaw Research, LLC, dated June 15, 2020 (incorporated by reference to Exhibit 10.10 of the Registrant's Registration Statement on Form S-1 (File No. 333-239412) filed on June 24, 2020).
10.10†*	Collaboration and License Agreement, by and between the Registrant and Genentech, Inc. and F. Hoffmann-La Roche Ltd, dated as of December 11, 2020.

10.11	Lease Agreement between the Registrant and ARE-MA REGION NO. 58, LLC, dated as of January 10, 2018 (incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1 (File No. 333-239412) filed on June 24, 2020).
10.12	Second Amendment to Lease, dated as of September 23, 2020, between the Registrant and ARE-MA REGION NO. 58, LLC (incorporated by reference to Exhibit 10.7 of the Registrant's Form 10-Q (File No. 001-39385) filed on November 12, 2020).
21.1*	List of Subsidiaries of Registrant.
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm.
24.1*	Power of Attorney (included on signature page).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

† Portions of this exhibit (indicated by asterisks) were omitted in accordance with the rules of the Securities and Exchange Commission.

# Indicates a management contract or any compensatory plan, contract or arrangement.

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**.**

Relay Therapeutics, Inc.

Date: March 25, 2021

By: /s/ Sanjiv K. Patel
Sanjiv K. Patel, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY AND SIGNATURES

Each person whose individual signature appears below hereby authorizes and appoints Sanjiv K. Patel, M.D. and Brian Adams, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his or her substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, 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/ Sanjiv K. Patel Sanjiv K. Patel, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 25, 2021
/s/ Thomas Catinazzo Thomas Catinazzo	Senior Vice President, Finance (Principal Accounting Officer and Principal Financial Officer)	March 25, 2021
/s/ Alexis Borisy Alexis Borisy	Director	March 25, 2021
/s/ Linda A. Hill Linda A. Hill, Ph.D.	Director	March 25, 2021
/s/ Douglas S. Ingram Douglas S. Ingram	Director	March 25, 2021
/s/ Mark Murcko Mark Murcko, Ph.D.	Director	March 25, 2021
/s/ Dipchand (Deep) Nishar Dipchand (Deep) Nishar	Director	March 25, 2021
/s/ Jami Rubin Jami Rubin	Director	March 25, 2021
/s/ Laura Shawver Laura Shawver, Ph.D.	Director	March 25, 2021

Exhibit 4.3

Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended

The summary of the general terms and provisions of the registered securities of Relay Therapeutics, Inc. ("Relay," "we," or "our") set forth below does not purport to be complete and is subject to and qualified in its entirety by reference to our Fourth Amended and Restated Certificate of Incorporation (our "certificate of incorporation") and our Amended and Restated Bylaws (our "bylaws" and, together with our certificate of incorporation, our "Charter Documents"), each of which is incorporated by reference as an exhibit to our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission. We encourage you to read our Charter Documents and the applicable provisions of the General Corporation Law of the State of Delaware (the "DGCL") for additional information.

General

Our authorized capital stock consists of One Hundred Fifty Million (150,000,000) shares of common stock, par value $0.001 per share and Ten Million (10,000,000) shares of undesignated preferred stock, par value $0.001 per share.

Common stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions. In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol "RLAY."
The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Preferred stock

Our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. No shares of preferred stock are outstanding, and we have no present plan to issue any shares of preferred stock.

Registration rights

Certain holders of our common stock, including those issuable upon the conversion of convertible preferred stock are entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of a second amended and restated investors' rights agreement between us and the holders of our preferred stock. The second amended and restated investors' rights agreement includes demand registration rights, short-form registration rights, and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand registration rights

Certain holders of our common stock, are entitled to demand registration rights. Under the terms of the second amended and restated investors' rights agreement, we will be required, upon the written request of a majority of holders of the registrable securities then outstanding that would result in an aggregate offering price of at least $7.5 million, to file a registration statement and to use commercially reasonable efforts to effect the registration of all or a portion of these shares for public resale.

Short-Form registration rights

Pursuant to our second amended and restated investors' rights agreement, if we are eligible to file a registration statement on Form S-3, upon the written request of at least 10% in interest of these holders to sell registrable securities at an aggregate price of at least $1.0 million, we will be required to use commercially reasonable efforts to effect a registration of such shares. We are required to effect only two registrations in any twelve-month period pursuant to this provision of the second amended and restated investors' rights agreement. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Piggyback registration rights

Pursuant to our second amended and restated investors' rights agreement, if we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions contained in the second amended and restated investors' rights agreement, we and the underwriters may limit the number of shares included in the underwritten offering to the number of shares which we and the underwriters determine in our sole discretion will not jeopardize the success of the offering.

Indemnification

Our second amended and restated investors' rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expiration of registration rights

The demand registration rights and short form registration rights granted under our second amended and restated investors' rights agreement will terminate on the fifth anniversary of the completion of our initial public offering.

Anti-Takeover effects of our certificate of incorporation and bylaws and Delaware law

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board composition and filling vacancies

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No written consent of stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance notice requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to certificate of incorporation and bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, and limitation of liability must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of a majority of the outstanding shares entitled to vote on the amendment, voting together as a single class, except that the amendment of the provisions relating to notice of stockholder business and nominations and special meetings must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote.

Undesignated preferred stock

Our certificate of incorporation provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of

preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of forum

Our bylaws provide that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware (or, if the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. Our bylaws also provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

In addition, our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the United States District Court in the District of Massachusetts will be the exclusive forum for any private action asserting violations by us or any of our directors or officers of the Securities Act or the Exchange Act, or the rules and regulations promulgated thereunder, and of all suits in equity and actions at law brought to enforce any liability or duty created by those statutes or the rules and regulations under such statutes. If any action the subject matter of which is within the scope of the preceding sentence is filed in a court other than the United States District of Massachusetts, the plaintiff or plaintiffs shall be deemed by this provision of the bylaws (i) to have consented to removal of the action by us to the United States District Court in the District of Massachusetts, in the case of an action filed in a state court, and (ii) to have consented to transfer of the action to the United States District Court in the District of Massachusetts.

Section 203 of the Delaware general corporation law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
  subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Exhibit 10.10

EXECUTION COPY
CONFIDENTIAL

Certain identified information has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark [***].

COLLABORATION AND LICENSE AGREEMENT

between

GENENTECH, INC. and F. HOFFMANN-LA ROCHE LTD

and

RELAY THERAPEUTICS, INC.

Dated as of December 11, 2020

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LIST OF SCHEDULES

COLLABORATION AND LICENSE AGREEMENT

This **LICENSE AGREEMENT** (this "**Agreement**") is entered into as of December 11, 2020 (the "**Execution Date**") by and between Genentech, Inc., a corporation organized and existing under the laws of the State of Delaware and having its principal place of business at 1 DNA Way, South San Francisco, CA 94080 ("**Genentech**") and F. Hoffmann-La Roche Ltd, having a principal place of business at Grenzacherstrasse 124, CH 4070 Basel, Switzerland ("**Roche**") (Genentech and Roche, together, "**Licensee**"), on the one hand, and Relay Therapeutics, Inc., a corporation organized and existing under the laws of the State of Delaware and having its principal place of business at 399 Binney Street, 2nd Floor, Cambridge, Massachusetts 02139 ("**Relay**"), on the other hand. Licensee and Relay are each referred to herein by name or as a "**Party**", or, collectively, as the "**Parties**".

RECITALS

WHEREAS, Relay is a clinical-stage precision medicines company transforming the drug discovery process with a focus on enhancing small molecule therapeutic discovery in targeted oncology;

WHEREAS, Licensee possesses expertise in the development and commercialization of pharmaceutical products; and

WHEREAS, Licensee desires to obtain an exclusive license and other rights from Relay for the Research, Development, Manufacture and Commercialization of Licensed Candidates and Licensed Products, and Relay agrees to grant Licensee such an exclusive license, on the terms and conditions set forth herein;

WHEREAS, Licensee and Relay desire to conduct certain Development activities, to provide Relay with the option to share the costs of Development and profits and losses collaborate with respect to Lead Products, and to permit Relay to Develop and Commercialize certain compounds for Combination Use with Licensed Products in the Field in the Territory, in each case on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1.
DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms will have the respective meanings set forth below.

1.1 "**1971 Patent**" means any Relay Patent that claims a Lead Candidate or Lead Product.

1.2 "**Accounting Standards**" means, with respect to either Party, generally accepted accounting principles as applicable in the United States or International Financial Reporting

Standards of the International Accounting Standards Board ("**IFRS**"), in each case, as generally and consistently applied throughout such Party's organization. Each Party will promptly notify the other Party in writing if such Party changes the Accounting Standards pursuant to which its records are maintained.

1.3 "**Acquired Program**" has the meaning set forth in Section 9.2.1.

1.4 "**Acquirer**" means, collectively, the Third Party referenced in the definition of Change of Control and such Third Party's Affiliates (as of the Change of Control or thereafter), other than the applicable Party in the definition of Change of Control and such Party's Affiliates, determined as of immediately prior to the closing of such Change of Control.

1.5 "**Acquirer Program**" has the meaning set forth in Section 9.3.

1.6 "**Action**" means any claim, action, suit, arbitration, inquiry, audit, proceeding or investigation by or before, or otherwise involving, any Governmental Authority.

1.7 "**Affiliate**" means, with respect to any Person, any other Person, as of the Execution Date or at any time during the Term, directly or indirectly controlling or controlled by, or under direct or indirect common control with, such first Person. For purposes of this definition, a Person will be deemed, in any event, to control another Person if it (a) owns or controls, directly or indirectly, or has the ability to direct or cause the direction or control of, more than fifty percent (50%) of the voting equity of such other Person, or (b) has the ability to direct, cause the direction of or control the management or policies of such other Person, whether through direct or indirect ownership of voting equity, by contract or otherwise. For purposes of this definition, the term "**control**", "**controlled**" or "**controlling**" means (i) the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such entity, whether through the ownership of voting securities, by contract or otherwise, or (ii) when used with respect to any security, the possession, directly or indirectly, of the power to vote, or to direct the voting of, such security or the power to dispose of, or to direct the disposition of, such security. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside the United States, the maximum percentage of ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage will be substituted in the preceding sentence; provided that such foreign investor has the power to direct the management and policies of such entity. Notwithstanding anything in the foregoing of this Section 1.7, for purposes of this Agreement, [***].

1.8 "**Agreement**" has the meaning set forth in the preamble hereto.

1.9 "**Alliance Manager**" has the meaning set forth in Section 10.13.

1.10 "**Allowable Expenses**" [***].

1.11 "**ANDA**" means an Abbreviated New Drug Application and all amendments and supplements thereto filed with the FDA under Section 505(j) of the FDCA (21 U.S.C. 355(j)), or the equivalent application filed with any equivalent Regulatory Authority outside the United States (including any supra national agency).

1.12 **"Antitrust Counsel Only Material**" has the meaning set forth in Section 17.2.4.

1.13 "**Antitrust Law**" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder (the "**HSR Act**"), the Sherman Act, as amended, the Clayton Act, as amended, the Federal Trade Commission Act, as amended, and any other Applicable Law of the United States, a state or territory thereof, or any foreign government or supranational body (including the European Commission) that are designed to prohibit, restrict or regulate actions having the purpose or effect of monopolization, restraint of trade, or lessening of competition through merger or acquisition.

1.14 "**Applicable Law**" means any applicable federal, state, local or foreign constitution, treaty, law, statute, ordinance, rule, regulation, standard, interpretation, guidance document, directive, policy, order, writ, award, decree, injunction, judgment, stay or restraining order of any Governmental Authority, the terms of any permit, certificate, or authorization, and any other ruling or decision of, agreement with or by, or any other requirement of, any Governmental Authority having proper jurisdiction over the matter, including, to the extent applicable, the Federal Food, Drug, and Cosmetic Act ("**FDCA**"), as amended, the Public Health Service Act ("**PHSA**"), as amended, United States Department of Health and Human Services ("**HHS**") privacy rules under the Health Insurance Portability and Accountability Act, as amended, and the General Data Protection Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

1.15 "**Back-Up Compound**" means any compound that is Directed to the Collaboration Target, other than the Lead Candidate, that is disclosed in a Relay Patent or a Joint Collaboration Patent.

1.16 "**Back-Up Development/Commercial Milestone**" has the meaning set forth in Section 11.5.3.

1.17 "**Back-Up Development/Commercial Milestone Payment**" has the meaning set forth in Section 11.5.3.

1.18 "**Back-Up Product**" means any Licensed Product that constitutes, comprises or contains any Back-Up Compound, regardless of its finished form, formulation or dosage. For clarity, a Back-Up Product cannot be a Lead Product or a Shared Product.

1.19 "**Back-Up Sales Milestone**" has the meaning set forth in Section 11.5.6.

1.20 "**Back-Up Sales Milestone Payment**" has the meaning set forth in Section 11.5.6.

1.21 "**Bankruptcy Code**" has the meaning set forth in Section 12.5.

1.22 "**Bulk Drug Product**" means formulated Bulk Drug Substance in bulk form prior to filling and finishing.

1.23 "**Bulk Drug Substance**" means a Licensed Candidate bulk form manufactured for use as an active pharmaceutical ingredient in a Licensed Product.

1.24 "**Business Day**" means any day excluding (a) Saturdays and Sundays; and (b) any day that is a legal holiday under the Applicable Law of the United States or Switzerland, or that is a day on which banking institutions located in San Francisco, California, Basel, Switzerland, or Boston, Massachusetts, are authorized or required by Applicable Law or other governmental action to close.

1.25 "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term will commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter will end on the last day of the Term.

1.26 "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term will commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term will commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.27 "**Change of Control**" means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the direct or indirect beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's and its controlled Affiliates' assets that relate to this Agreement; provided, however, that any public offering or any other bona fide capital raising event, public or private, a reorganization, spin-out, merger, consolidation or recapitalization, in each case, undertaken solely for tax planning purposes or solely to change a Party's domicile will not constitute a "Change of Control".

1.28 "[***].

1.29 "**Clinical Transfer**" has the meaning set forth in Section 3.2.4.

1.30 "**Clinical Trial**" means a human clinical trial and any such other tests and studies in human subjects that are required by Applicable Law, recommended by the Governmental Authorities, or are otherwise necessary to obtain or maintain Regulatory Approvals for a product.

1.31 "**CMO**" means any Third Party contract manufacturer.

1.32 "**Collaboration In-License**" has the meaning set forth in Section 11.6.4(d).

1.33 "**Collaboration Target**" [***] Src homology region 2 domain-containing phosphatase-2 (SHP2), [***].

1.34 "**Combination Product**" has the meaning set forth in Section 5.5.2(a).

1.35 "**Combination Use**" of a compound or product with one or more compounds or products means use of the first compound or product to be administered or dosed together, sequentially or concurrently, with one or more other compounds or products for the prevention or treatment of an Indication in patients.

1.36 "**Commercialization**" means any and all activities directed to the commercial manufacturing (including Manufacturing) or commercial supply of a product, marketing, detailing, promoting, advertising and seeking of pricing and reimbursement of such products (if applicable), whether before or after Regulatory Approval has been obtained (including making, having made, using, importing, selling and offering for sale such product), and will include marketing, promoting, advertising, detailing, market research, distributing, order processing, handling returns and recalls, booking sales, customer service, administering and commercially selling such products, importing, exporting or transporting such products for commercial sale, and all regulatory compliance with respect to the foregoing. When used as a verb, "**Commercialize**" means to engage in Commercialization.

1.37 "**Commercially Reasonable Efforts**" [***].

1.38 "**Competing Program**" has the meaning set forth in Section 13.8.

1.39 "**Competitive Infringement**" [***].

1.40 "**Competitive Product**" means any pharmaceutical product, other than a Relay Pipeline Combination, that is Directed to the Collaboration Target.

1.41 "**Composition of Matter Claim**" [***].

1.42 "**Compulsory Sublicense**" means, with respect to a Licensed Product, in a country, a license or rights granted to a Third Party (a "**Compulsory Sublicensee**") to sell or offer for sale such Licensed Product in such country under any Patent Controlled by Licensee (including any Patent licensed or sublicensed to Licensee under this Agreement)

(a) by a Governmental Authority within such country, without direct or indirect authorization from Licensee or any of its Affiliates, for example a right granted pursuant to requests under 30 August 2003 WTO decision, or

(b) by Licensee or any of its Affiliates if such grant is required by a Governmental Authority within such country for the purpose of enabling the Compulsory Sublicensee to sell Licensed Product for free or for a significantly reduced price.

1.43 "**Compulsory Sublicensee**" has the meaning set forth in Section 1.42.

1.44 "**Confidential Information**" means, with respect to a Party, all confidential information and materials, including Know-How, marketing plans, strategies, and customer lists, in each case, that are disclosed by or on behalf of such Party to the other Party, regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other Party by or on behalf of the Disclosing Party in oral, written, visual, graphic or electronic form. The Joint Collaboration Know-How is the Confidential Information of each Party, with each

Party treated as the Receiving Party. The [***] are the Confidential Information of each Party, with each Party treated as the Receiving Party.

1.45 "**Control**", "**Controls**" or "**Controlled**" means when used with respect to any item of Know-How, Regulatory Materials, Materials, Patent, or other intellectual property right, the possession (whether by ownership, license or sublicense, other than by a license, sublicense or other right granted (but not assignment) pursuant to this Agreement) by a Party of the ability (or the option to obtain the ability) to assign or grant to the other Party the licenses, sublicenses or rights to access and use such Know-How, Regulatory Materials, Materials, Patent, or other intellectual property right as provided for in this Agreement, without, other than with respect to any Existing Third Party Agreements and Collaboration In-Licenses, paying any consideration to any Third Party (now or in the future) or violating the terms of any agreement or other arrangement with any Third Party in existence as of the time such Party would be required hereunder to grant such license, sublicense or rights of access and use. Notwithstanding anything in this Agreement to the contrary, unless and until a Party (or its Affiliate) breaches Section 9.2.4, a Party will be deemed not to Control any Know-How, Regulatory Materials, Materials, Patent, or other intellectual property right that are owned or in-licensed by an Acquirer except (a) with respect to any such Know-How, Regulatory Materials, Materials, Patent, or other intellectual property right arising from active participation by employees or consultants of the Acquirer in connection with this Agreement after such Change of Control, (b) to the extent that any such Know-How, Regulatory Materials, Materials, Patent, or other intellectual property right is included in or used in furtherance of this Agreement by the Acquirer after such Change of Control, or (c) for Know-How, Regulatory Materials, Materials, Patent, or other intellectual property right constituting improvements (or direct improvements to such improvements) to the Relay IP or the Licensee IP (as applicable) in existence prior to such Change of Control created, conceived or generated by any employees or consultants of the Acquirer.

1.46 "**Coordinated Promotion Agreement**" has the meaning set forth in Section 5.6.2.

1.47 "**Coordinated Promotion Right**" has the meaning set forth in Section 5.6.1.

1.48 "**Core Countries**" [***].

1.49 "**Covered by**" or "**Cover**" or the like, means, with respect to a given Licensed Candidate or Licensed Product (as the case may be), that the sale, offer for sale or importation of such Licensed Candidate or Licensed Product, but for ownership of, or a license granted in this Agreement under, the relevant Patent would infringe a Valid Claim of such Patent (a) in the country of sale on the date of sale, in the case of royalty payments and (b) on the date a Development/Commercial Milestone, Opt-In Term Development/Commercial Milestone, or Back-Up Development/Commercial Milestone is achieved, in the case of a corresponding payments.

1.50 "**CRO**" means any Third Party contract research organization.

1.51 "**Cure Period**" has the meaning set forth in Section 16.3.

1.52 "**Deductible Third Party IP Payments**" has the meaning set forth in Section 11.6.4(g).

1.53 "**Deferred Combination Agent Election"** has the meaning set forth in 10.7.3(c).

1.54 "**Delegation of Authority**" has the meaning set forth in Section 3.4.1.

1.55 "**DESRES Agreement**" shall mean the Amended and Restated Collaboration and License Agreement by and between D.E. Shaw Research, LLC ("**DESRES**") and Relay Therapeutics, Inc., dated June 15, 2020.

1.56 "**Development**" means, for a compound or product, all activities, other than Research, necessary or reasonably useful or otherwise requested or required by a Governmental Authority as a condition or in support of obtaining or maintaining a Regulatory Approval, including pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, Clinical Trials, Manufacturing in support of Clinical Trials and other development activities, statistical analysis and report writing, the preparation and submission of applications for Regulatory Approvals, development activities conducted after receipt of Regulatory Approval pursuant to a request or requirement of Regulatory Authorities, pharmacoeconomic studies relating to the Indication for which the compound or product is being developed, and regulatory affairs with respect to the foregoing. When used as a verb, "**Develop**" means to engage in Development.

1.57 "**Development Costs**" [***].

1.58 "**Development/Commercial Milestone**" has the meaning set forth in Section 11.5.1.

1.59 "**Development/Commercial Milestone Payment**" has the meaning set forth in Section 11.5.1.

1.60 "**Development Know-How and Materials**" has the meaning set forth in Section 3.2.1

1.61 "**Development Milestone Composition of Matter Claim**" [***].

1.62 "**Development Transfer**" has the meaning set forth in Section 3.2.1(a).

1.63 "**Directed**" means, with respect to a pharmaceutical product and a protein, that such pharmaceutical product directly binds to, or is designed to directly bind to, such protein, and directly inhibits, or is designed to directly inhibit, the function of such protein.

1.64 "**Disclosing Party**" has the meaning set forth in Section 13.1.

1.65 "**Discontinued Relay Pipeline Combination Eligible Licensed Product**" has the meaning set forth in Section 16.9.1

1.66 "**Dispute**" has the meaning set forth in Section 18.9.1.

1.67 "**Distributor**" means any Person appointed by Licensee or any of its Affiliates or any Licensee Sublicensee to distribute, market and sell the Licensed Products in one or more countries in the Territory, in circumstances where the Person purchases its requirements of the Licensed Products from Licensee or its Affiliates or any Licensee Sublicensee but does not otherwise make any royalty or other payment to Licensee or its Affiliates or any Licensee Sublicensee with respect to its rights under the Relay IP or Licensee Collaboration IP.

1.68 "**Dollars**" or "**$**" means the legal tender of the United States.

1.69 **"Early Payment Election"** has the meaning set forth in Section 3.8.3(b).

1.70 "**Effective Date**" has the meaning set forth in Section 17.1.

1.71 "**EMA**" has the meaning set forth in Section 1.211.

1.72 "**Enforcing Party**" has the meaning set forth in Section 12.9.4(a).

1.73 "**EU**" means the European Union and all its then-current member countries, but including in any case France, Germany, Italy, Spain and the United Kingdom regardless of whether they are then-current member countries.

1.74 "**Exchange**" has the meaning set forth in Section 13.3.1(a).

1.75 "**Execution Date**" has the meaning set forth in the preamble hereto.

1.76 "**Executive Officers**" means (a) with respect to Relay, Relay's Chief Executive Officer or his or her designee with appropriate decision-making authority and (b) with respect to Licensee, a Vice President of Genentech or his or her designee with appropriate decision-making authority.

1.77 "**Existing Sponsored Research Agreements**" [***].

1.78 "**Existing Third Party Agreement**" means any agreement with a Third Party in effect as of the Effective Date pursuant to which Relay Controls any Relay Patents or Relay Know-How.

1.79 "**Expert**" means a Person with no less than ten (10) years of experience in the pharmaceutical and life sciences industries, but excluding any current or former employee or consultant of either Party. Such Person will be fluent in the English language.

1.80 "**FDA**" has the meaning set forth in Section 1.211.

1.81 "**FDCA**" has the meaning set forth in Section 1.14.

1.82 "**FGFR2**" [***].

1.83 "**Field**" [***].

1.84 "**Financial Committee**" has the meaning set forth in Section 18.9.4(a).

1.85 "**Financial Dispute**" means any Dispute related to determining the Relative Commercial Value pursuant to Section 5.5.2(e) in connection with a Combination Product.

1.86 "**Financial Expert**" means a Person with no less than ten (10) years of experience in the pharmaceutical and life sciences industries, with expertise in the valuation of pharmaceutical products, but excluding any current or former employee or consultant of either Party. Such Person will be fluent in the English language.

1.87 "**Financial Liaison**" has the meaning set forth in Section 10.12.

1.88 "**Financial Report**" has the meaning set forth in Section 18.9.4(b).

1.89 "**Finished Product**" means the finished product formulation of a Licensed Product, containing Bulk Drug Product, filled into unit packages for final labeling and packaging.

1.90 "**First Commercial Sale**" [***].

1.91 "**First Tier GDP Overrun**" has the meaning set forth in Section 3.8.5.

1.92 "**Fixed SG&A**" means the amount calculated by multiplying the Fixed SG&A Percentage by the Net Sales amount.

1.93 "**Fixed SG&A Percentage**" [***].

1.94 "**Force Majeure Event**" has the meaning set forth in Section 18.1.

1.95 "**FTE**" means a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed by a Party (or any of its Affiliates) and assigned to perform specific work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof will be [***] per year.

1.96 "**FTE Costs**" [***].

1.97 "**GCP**" means the applicable then-current ethical and scientific quality standards for designing, conducting, overseeing, monitoring, recording, and reporting trials that involve the participation of human subjects as are required by applicable Regulatory Authorities or Applicable Law in the relevant jurisdiction, including in the United States the regulations at 21 C.F.R. Parts 50, 54, 56, and 312 and FDA guidance documents (including Guideline for Good Clinical Practice – ICH Harmonized Tripartite Guideline (ICH E6)), and, outside the United States, Guidelines for Good Clinical Practice – ICH Harmonized Tripartite Guideline (ICH E6).

1.98 "**Genentech**" has the meaning set forth in the preamble hereto.

1.99 "**Generic Product**" [***].

1.100 "**Generic Relay Combination Patent**" [***].

1.101 "**Global Development Budget**" means a budget for the Development Costs for the Lead Products covered by the GDP in the Field in the Territory.

1.102 "**Global Development Plan**" or "**GDP**" means a written development plan that includes (a) a Global Development Budget, and (b) a description of Development activities (other than the Relay Phase Ia Trial) for Development of the Lead Products other than those [***] Combination Agents for which Relay issued a Deferred Combination Agent Election pursuant to Section 10.7.3(c), in the Field in the Territory designed, to the extent supported by scientific evidence, to obtain Regulatory Approval for the Lead Products to the extent such activities can be reasonably determined at the time. An initial draft of the Global Development Plan is attached as 1.102.

1.103 "**Global Trial**" has the meaning set forth in Section 3.8.2.

1.104 "**GLP**" means the applicable then-current good laboratory practice standards promulgated or endorsed by the FDA, as defined in the United States in 21 C.F.R. Part 58 and relevant guidance documents, or such other comparable regulatory standards in jurisdictions outside the United States as promulgated or endorsed by the applicable Regulatory Authorities.

1.105 "**GMP**" means all applicable standards relating to current good manufacturing practices for fine chemicals, intermediates, bulk products, biologic components, raw materials or finished biological or pharmaceutical products, including (a) all applicable requirements under 21 U.S.C. § 351(a)(2)(B) and in the FDA's current Good Manufacturing Practices regulations at 21 C.F.R. Parts 210, 211, 600, and 610 and relevant guidance documents, (b) all applicable requirements detailed in the EMA's "The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products", and (c) all analogous Applicable Law promulgated by any Governmental Authority having jurisdiction over the manufacture of the applicable biological or pharmaceutical compound or product.

1.106 "**Governmental Authority**" means any (a) federal, state, local, municipal, foreign or other government, (b) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, licensing body, officer, official, representative, organization, unit, body or entity and any court or other tribunal of competent jurisdiction (including any arbitration or other alternative dispute forum)), (c) supra-national or multinational governmental organization or body or (d) entity or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature. The term "Governmental Authority" includes any Regulatory Authority.

1.107 "**gRED**" means the Research and Early Development organization of Genentech (or its equivalent, if reorganized).

1.108 "**HHS**" has the meaning set forth in Section 1.14.

1.109 "**HSR Act**" has the meaning set forth in Section 1.13.

1.110 "**HSR Clearance Date**" means the earliest date on which the Parties have actual knowledge that all applicable waiting periods and requests for information (and any extensions

thereof) under the HSR Act with respect to the transactions contemplated by this Agreement have expired or have been terminated.

1.111 "**Immediate Tech Transfer Activities**" has the meaning set forth in Section 11.1.1.

1.112 "**In-License Payments**" [***].

1.113 "**IND**" means an investigational new drug application (including any amendment or supplement thereto) submitted to the FDA pursuant to U.S. 21 C.F.R. Part 312. References herein to IND will include, to the extent applicable, any comparable filing(s) outside the U.S. for the investigation of any product in any other country or group of countries (such as a Clinical Trial Application in the EU).

1.114 "**IND Transfer Milestone**" has the meaning set forth in Section 11.1.2.

1.115 "**Indemnification Claim Notice**" has the meaning set forth in Section 15.3.1.

1.116 "**Indemnified Party**" has the meaning set forth in Section 15.3.1.

1.117 "**Indemnifying Party**" has the meaning set forth in Section 15.3.1.

1.118 "**Indication**" [***].

1.119 "**Initiation**" means, with respect to a given Clinical Trial, the administration of the first dose of a Licensed Product to the first subject in such Clinical Trial in accordance with the protocol for such Clinical Trial. Cognates of the word "Initiation" will have correlative meanings.

1.120 "**Inventory**" means the materials to be transferred by Relay or on its behalf to Licensee or its CMO as set forth on the Technology Transfer Plan, [***].

1.121 "**JDT**" has the meaning set forth in Section 10.1.

1.122 "**Joint Collaboration IP**" means collectively the Joint Collaboration Know-How and Joint Collaboration Patents.

1.123 "**Joint Collaboration Know-How**" means any Know-How that is first created, conceived or generated jointly by or on behalf of Licensee or its Affiliates (or their respective Third Party Subcontractors), on the one hand, and Relay or its Affiliates (or their respective Third Party Subcontractors), on the other hand, as determined pursuant to Section 12.7.1 in the course of activities performed under this Agreement.

1.124 "**Joint Collaboration Patents**" means any Patents that claim any Joint Collaboration Know-How.

1.125 "**Joint Team**" means each of the (a) JDT and (b) JPT.

1.126 "**Joint Third Party Action**" has the meaning set forth in Section 12.11.2.

1.127 "**JPT**" has the meaning set forth in Section 10.1.

1.128 "**Know-How**" [***].

1.129 "**Knowledge**" means, with respect to a Party, the actual knowledge of any employees of such Party (including in such Party's internal legal department and intellectual property group) who were directly involved in the negotiation of this Agreement with the other Party, without any duty to conduct any investigation.

1.130 "**[***]**.

1.131 "**Launch Costs**" [***].

1.132 "**Lead Candidate**" [***] Relay's proprietary compound RLY-1971 [***].

1.133 "**Lead Product**" [***]

1.134 "**Lead Royalty Product**" means, (a) during the Opt-In Term, each Lead Product but solely with respect to the Royalty Territory and (b) before or after the Opt-In Term, each Lead Product in the Territory.

1.135 "**Licensed Candidate**" means the Lead Candidate and any Back-Up Compound.

1.136 "**Licensed Product**" [***].

1.137 "**Licensee Collaboration IP**" means any (a) Know-How first created, conceived or generated by or on behalf of Licensee or its Affiliates (whether solely or jointly with any Third Party(ies)), in the course of activities performed under this Agreement, as determined pursuant to Section 12.7.1, and (b) Patents that claim such Know-How, but excluding, in each case of (a) and (b), Joint Collaboration IP.

1.138 "**[***] Combination**" means any Combination Use of a Licensed Candidate or Licensed Product with one or more other compounds or products, [***].

1.139 "**[***]**.

1.140 "**Licensee IP**" means Licensee Collaboration IP and Licensee's interest in Joint Collaboration IP.

1.141 "**[***] Agent**" [***].

1.142 "**[***] Agent Product**" [***].

1.143 "**[***] Back-Up Combination**" [***].

1.144 "**[***] Combination**" means the Combination Use of (a) one or more [***] Agents or [***] Agent Products with (b) the Lead Candidate or a Lead Product (and which may include Combination Use with one or more other compounds or products in addition). [***].

1.145 "[***].

1.146 "[***].

1.147 "[***].

1.148 "**[***] Other Back-Up Combination**" means the Combination Use of (a) one or more compounds or products [***] other than a [***] Agent or [***] Agent Product with (b) a Back-Up Compound or a Back-Up Product. For clarity, [***] Other Back-Up Combinations exclude use of the compounds or products described in clause (a) above as a monotherapy or in combination with one or more compounds or products without a Back-Up Compound or a Back-Up Product and further exclude [***] Back-Up Combinations.

1.149 "**[***] Other Combination**" means the Combination Use of (a) one or more compounds or products [***], other than a [***] Agent or [***] Agent Product, with (b) the Lead Candidate or a Lead Product. For clarity, [***] Other Combinations exclude use of the compounds or products described in clause (a) above as a monotherapy or in combination with one or more compounds or products without the Lead Candidate or a Lead Product and further exclude [***] Combinations.

1.150 "**[***] Pipeline Compound**" has the meaning set forth in Section 11.6.4(b).

1.151 "**Licensee Selection Data Package**" has the meaning set forth in Section 3.8.3(a).

1.152 "**Licensee Selection Data Package Review Period**" has the meaning set forth in Section 3.8.3(b).

1.153 "**Licensee Sublicensee**" means a Third Party to which Licensee (or its Affiliate) has, pursuant to Section 12.2, granted sublicense rights under any of the license rights granted under Section 12.1.1 or to any Licensed Candidate or Licensed Product, but excluding Distributors and Compulsory Sublicensees.

1.154 "**Losses**" means all losses, costs, claims, damages, liabilities and expense (including reasonable attorneys' fees and other reasonable Out-of-Pocket Costs of litigation).

1.155 "**Major Market Countries**" [***].

1.156 "**Major Market Country in the EU**" [***].

1.157 "**Manufacture**" means all activities related to the manufacturing of a product or, in either case, any raw material, component or ingredient thereof, including test method development and stability testing, formulation, cell line development, process development and validation, manufacturing scale-up whether before or after Regulatory Approval, manufacturing any product in bulk or finished form for Development or Commercialization (as applicable), including filling and finishing, packaging, labeling, shipping and holding, in-process and Finished Product testing, release of a product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of a product and regulatory activities

related to any of the foregoing. Cognates of the word "Manufacture" will have correlative meanings.

1.158 "**Manufacturing Costs**" [***].

1.159 "**Manufacturing Know-How and Materials**" has the meaning set forth in Section 3.2.2

1.160 "**Manufacturing Transfer**" has the meaning set forth in Section 3.2.2.

1.161 "**Marketing Studies**" mean human clinical trials of a Licensed Candidate or Licensed Product conducted following Initiation of a Pivotal Trial for such Licensed Candidate or Licensed Product that is not required for receipt of Regulatory Approval (whether such human clinical trial is conducted prior to or after receipt of such Regulatory Approval) and is not a Post-Approval Study, but that may be useful in support of the post-Regulatory Approval exploitation of such Licensed Candidate or Licensed Product.

1.162 "**Material Communications**" means any material written, electronic, telephonic, or in person communications from or with any Regulatory Authority, including but not limited to any of the following: potential labeling changes, key product quality attributes (e.g., purity), product manufacturing, safety findings (e.g., serious adverse events, emerging safety signals, imposition of a clinical hold), clinical or non-clinical findings that may affect patient safety, lack of efficacy, receipt or denial of Regulatory Approval, the conduct or design of Clinical Trials, or the need for additional non clinical studies (e.g., additional toxicology or carcinogenicity studies) or Clinical Trials.

1.163 "**Materials**" all tangible compositions of matter, devices, articles of manufacture, assays, biological, chemical, or physical materials, and other similar materials.

1.164 "**Medical Affairs**" means the coordination of medical information requests and field based medical scientific liaisons with respect to a Shared Product (including any [***] Combinations), including activities of medical scientific liaisons, activities involving key opinion leaders, and the provision of medical information services with respect to such Shared Product.

1.165 "**Merger Control Filing**" means any filing by Relay or Licensee with (a) the U.S. Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, or (b) with any other Governmental Authority of any merger control filing required under applicable Antitrust Law, in each case, together with all required documentary attachments thereto.

1.166 "**NDA**" means any (a) New Drug Application pursuant to the FDCA submitted to the FDA, or (b) a substantially similar application or submission submitted to a Regulatory Authority in a country or group of countries within the Territory to obtain Regulatory Approval (but not Pricing Approval) to Commercialize a Licensed Candidate or Licensed Product in that country or in that group of countries, including, with respect to the EU, a Marketing Authorization Application submitted to the EMA pursuant to the centralized approval procedure or to the

applicable Regulatory Authority of a country in the EU with respect to the mutual recognition or any other national approval.

1.167 "**Net Profits and Net Losses**", [***].

1.168 "**Net Sales**" [***].

1.169 "**Non-Publishing Party**" has the meaning set forth in Section 13.5.

1.170 "**Opt-In Data Package**" has the meaning set forth in Section 4.1.2.

1.171 **"Opt-In Deadline"** has the meaning set forth in Section 4.1.2.

1.172 "**Opt-In Effective Date**" has the meaning set forth in Section 4.1.6.

1.173 "**Opt-In Exercise Notice**" has the meaning set forth in Section 4.1.6.

1.174 "**Opt-In Right**" has the meaning set forth in Section 4.1.1.

1.175 "**Opt-In Sales Milestone**" has the meaning set forth in Section 11.5.5.

1.176 "**Opt-In Sales Milestone Payment**" has the meaning set forth in Section 11.5.5.

1.177 "**Opt-In Term**" means the period of time from the Opt-In Effective Date until the Opt-Out Date.

1.178 "**Opt-In Term Development/Commercial Milestone**" has the meaning set forth in Section 11.5.2.

1.179 "**Opt-In Term Development/Commercial Milestone Payment**" has the meaning set forth in Section 11.5.2.

1.180 "**Opt-Out Date**" has the meaning set forth in Section 4.2.1.

1.181 "**Opt-Out Right**" has the meaning set forth in Section 4.2.1.

1.182 "**Optional Additional Phase Ia Study"** has the meaning set forth in Section 3.3.2.

1.183 "**Other Shared Expenses**" [***].

1.184 "**Out-of-Pocket Costs**" [***].

1.185 "**Party**" or "**Parties**" has the meaning set forth in the preamble hereto.

1.186 "**Patent Challenge**" has the meaning set forth in Section 16.5.

1.187 "**Patents**" [***].

1.188 "**Pending Claim**" [***].

1.189 "**Person**" means an individual, corporation, partnership, limited liability company, joint venture, association, trust, unincorporated organization or other entity or any Governmental Authority.

1.190 "**Pharmacovigilance Agreement**" has the meaning set forth in Section 6.6.

1.191 "**Phase I Clinical Trial**" means a Clinical Trial conducted in healthy volunteers or patients to obtain initial information on a drug's safety, tolerability, pharmacological activity or pharmacokinetics, as more fully defined in 21 C.F.R. § 312.21(a) or its foreign equivalents.

1.192 "**Phase Ia Clinical Trial**" means a Clinical Trial, the principal purpose of which is a preliminary determination of safety, pharmacokinetic, and pharmacodynamic parameters in healthy individuals or patients, or a similar Clinical Trial.

1.193 "**Phase Ia Product**" means the pharmaceutical product that contains the Lead Candidate that is the subject of the Relay Phase Ia Trial and was manufactured for Relay for use in such trial.

1.194 "**Phase Ib Clinical Trial**" means a Clinical Trial: (a) the principal purpose of which is to evaluate safety and tolerability following repeat dosing in patients and (b) the secondary purpose of which may be to evaluate biomarker-based or clinical endpoint-based trends of efficacy, conducted after the initiation of an initial Phase I Clinical Trial or Phase Ia Clinical Trial. A Phase Ib Clinical Trial may be prospectively designed to generate sufficient data (if successful) to commence a Phase II Clinical Trial or a Phase III Clinical Trial or, in some instances, to submit an application for Regulatory Approval, which may include accelerated approval under section 506(c) of the FDCA or conditional approval under analogous Applicable Law in other countries.

1.195 "**Phase II Clinical Trial**" means a controlled Clinical Trial conducted to evaluate the safety, dosing, and effectiveness of a drug for a particular Indication or Indications in patients with the disease or condition of interest as more fully defined in 21 C.F.R. §312.21(b) or its foreign equivalents. A Phase II Clinical Trial may be prospectively designed to generate sufficient data (if successful) to commence a Phase III Clinical Trial or, in some instances, to submit an application for Regulatory Approval, which may include accelerated approval under section 506(c) of the FDCA or conditional approval under analogous Applicable Law in other countries.

1.196 "**Phase III Clinical Trial**" means a controlled Clinical Trial with a patient population randomized to receive experimental or standard therapy to demonstrate the effects of the experimental therapy compared to standard therapy, performed after preliminary evidence suggesting effectiveness of a drug has been obtained, and is designed to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug, provide an adequate basis for physician labeling, and generate sufficient data to file for Regulatory Approval, as more fully defined in 21 C.F.R. §312.21(c) or its foreign equivalents.

1.197 "**PHSA**" has the meaning set forth in Section 1.14.

1.198 "**PIK3CA**" [***].

1.199 "**Pivotal Trial**" means, with respect to any compound or product, a Clinical Trial that at the time of Initiation (or any later point, if applicable), is expected, based on guidance from the FDA or other applicable Regulatory Authority or otherwise, to provide the basis for submitting an application for Regulatory Approval for such compound or product. For avoidance of doubt, a Clinical Trial or portion thereof may be a Pivotal Trial regardless of whether the protocol for such Clinical Trial describes it as a Phase II Clinical Trial, Phase III Clinical Trial or any variation thereof, including but not limited to a Phase II/III Clinical Trial or Phase IIb Clinical Trial.

1.200 "**Post-Approval Study**" means a Clinical Trial or other nonclinical studies, whether required by a Regulatory Authority or not, of a Licensed Candidate or a Licensed Product initiated in a country after receipt of Regulatory Approval for such Licensed Candidate or Licensed Product in such country.

1.201 "**Pricing Approval**" means any governmental approval, agreement, determination, or decision establishing the prices for a product that can be charged or reimbursed in regulatory jurisdictions where the applicable Governmental Authorities negotiate, approve, or determine the price or reimbursement of biological or pharmaceutical products.

1.202 "**Prior Agreement Third Party IP**" has the meaning set forth in Section 11.6.4(e).

1.203 "**Profit Share Territory**" means the United States.

1.204 "**Proposed Relay Pipeline Combination Development Plan**" has the meaning set forth in Section 3.7.2.

1.205 "**Prosecution and Maintenance**" or "**Prosecute and Maintain**" means, with regard to a Patent, the preparation, filing, prosecution and maintenance of such Patent, as well as reissues and appeals with respect to such Patent, together with the initiation or defense of interferences, derivation proceedings, post-grant proceedings, oppositions and other similar proceedings with respect to the particular Patent, and any appeals therefrom. For clarification, "Prosecution and Maintenance" or "Prosecute and Maintain" will not include any other enforcement or defense actions taken with respect to a Patent.

1.206 "**Publications**" has the meaning set forth in Section 13.6.

1.207 "**Publishing Party**" has the meaning set forth in Section 13.5.

1.208 "**Quality Agreement**" has the meaning set forth in Section 3.3.9.

1.209 "**Receiving Party**" has the meaning set forth in Section 13.1.

1.210 "**Regulatory Approval**" means all approvals, licenses, permits, certifications, and authorizations of the applicable Regulatory Authority necessary for the development, manufacture, marketing and sale of a biological or pharmaceutical product in a country in the world, including Pricing Approvals. For avoidance of doubt, "Regulatory Approval" includes accelerated approval under section 506(c) of the FDCA or conditional approval under analogous Applicable Law in other countries.

1.211 "**Regulatory Authority**" means any national or supranational Governmental Authority, including the UK Medicines and Healthcare products Regulatory Agency (and any successor entity thereto) in the UK, the U.S. Food and Drug Administration (and any successor entity thereto) (the "**FDA**") in the U.S., the European Medicines Agency (and any successor entity thereto) (the "**EMA**") in EU and the Ministry of Health, Labour and Welfare of Japan, or the Pharmaceuticals and Medical Devices Agency of Japan (or any successor to either of them) as the case may be in Japan, or any health regulatory authority in any country or region in the Territory that is a counterpart to the foregoing agencies, in each case, that grants of Regulatory Approval for a biological, or pharmaceutical product, as applicable, in such country or region.

1.212 "**Regulatory Expenses**" [***].

1.213 "**Regulatory Lead**" means [***].

1.214 "**Regulatory Materials**" means the regulatory registrations, listings, applications, licenses, certifications, authorizations, approvals and other submissions or filings made to or received from any Regulatory Authority for research, development (including the conduct of Clinical Trials), manufacture, distribution, or commercialization of a biological or pharmaceutical product in a regulatory jurisdiction, together with all related correspondence to or from any Regulatory Authority and all documents referenced in the complete regulatory chronology for each Regulatory Approval, including all drug master files (if any), INDs, supplements and amendments thereto, and foreign equivalents of any of the foregoing.

1.215 "**Regulatory Transfer**" has the meaning set forth in Section 3.2.3.

1.216 "**Relative Commercial Value**" has the meaning set forth in Section 5.5.2(e).

1.217 "**Relay**" has the meaning set forth in the preamble hereto.

1.218 "**Relay Collaboration Know-How**" means any Know-How first created, conceived or generated by or on behalf of Relay or its Affiliates (whether solely or jointly with any Third Party(ies)) in the course of activities performed under this Agreement, as determined pursuant to Section 12.7.1, but excluding Joint Collaboration Know-How.

1.219 "**Relay Collaboration Patents**" means any Patents that claim Relay Collaboration Know-How.

1.220 "**Relay Combination Collaborator**" has the meaning set forth in Section 12.2.

1.221 "**Relay Combination Patent**" [***].

1.222 "**Relay IND Transfer**" has the meaning set forth in Section 3.2.3.

1.223 "**Relay IND Transfer Date**" means the date on which the Relay IND Transfer is complete.

1.224 "**Relay IP**" means all Relay Patents, Relay Know-How, and Relay's interest in Joint Collaboration IP.

1.225 "**Relay Know-How**" [***].

1.226 "**Relay Patents**" [***].

1.227 "**Relay Phase Ia Plan**" has the meaning set forth in Section 3.3.

1.228 "**Relay Phase Ia Trial**" [***].

1.229 "**Relay Phase Ia Trial CRO**" [***].

1.230 "**Relay Phase Ia Trial CRO Costs**" [***].

1.231 "**Relay Phase Ia Trial Data**" has the meaning set forth in Section 3.2.4(c).

1.232 "**Relay Phase Ia Trial Milestone**" has the meaning set forth in Section 11.1.3.

1.233 "**Relay Pipeline Combination**" means the Combination Use of a Relay Pipeline Compound or Relay Pipeline Product with a Relay Pipeline Combination Eligible Licensed Product. [***].

1.234 "**Relay Pipeline Combination Eligible Licensed Product**" means, in connection with a Relay Pipeline Combination, a Licensed Candidate or Licensed Product [***].

1.235 "**Relay Pipeline Combination Eligible Licensed Product Cessation**" has the meaning set forth in Section 16.9.1.

1.236 "**Relay Pipeline Combination Eligible Licensed Product Discontinuation Notice**" has the meaning set forth in Section 16.9.1.

1.237 "**Relay Pipeline Compound**" [***] RLY-4008 or RLY-PI3K1047, [***].

1.238 "**Relay Pipeline Product**" means a product that constitutes, comprises or contains a Relay Pipeline Compound. [***].

1.239 "**Relay Royalty Patent**" [***].

1.240 "**Relay Sublicensee**" means a Third Party to which Relay (or its Affiliate) has (a) pursuant to Section 12.2, granted sublicense rights under any of the license rights granted under Section 12.1.2 or (b) granted a license under any of the rights retained by Relay pursuant to Section 12.1.1. in each case ((a) and (b)), with respect to a Relay Pipeline Combination, but excluding Distributors.

1.241 "**Required Additional Phase Ia Study"** has the meaning set forth in Section 3.3.2.

1.242 "**Research**" means with respect to a compound or product, any research activities with respect to such compound or product.

1.243 "**Right of Reference**" has the meaning set forth in Section 6.4.

1.244 "**Royalty Products**" means, (a) the Lead Royalty Products and (b) all Back-Up Products.

1.245 "**Royalty Term**" [***].

1.246 "**Royalty Territory**" means the Territory, other than the Profit Share Territory.

1.247 "**Rules**" has the meaning set forth in Section 18.10.1.

1.248 "**SAE Management Plan**" has the meaning set forth in Section 3.3.8.

1.249 "**Sales**" [***].

1.250 "**Sales Milestone**" has the meaning set forth in Section 11.5.4.

1.251 "**Sales Milestone Payment**" has the meaning set forth in Section 11.5.4.

1.252 **"Second Tier GDP Overrun**" has the meaning set forth in Section 3.8.5.

1.253 "**Shared Collaboration In-License Payments**" has the meaning set forth in Section 11.6.4(f).

1.254 "**Shared Products**" means the Lead Products solely during the Opt-In Term. For clarity, if Relay exercises its Opt-In Right and later exercises its Opt-Out Right, all Shared Products will automatically become Royalty Products.

1.255 "**Sharing Percentages**" [***] Net Profits and Net Losses, fifty percent (50%) for Relay and fifty percent (50%) for Licensee for the Profit Share Territory. [***].

1.256 "**Sponsor**" is defined in 21 CFR § 312.3(b) and, with respect to a Clinical Trial under this Agreement, means the entity that takes responsibility for the Clinical Trial in any jurisdiction.

1.257 "**Subcontracting Party**" has the meaning set forth in Section 8.1.4.

1.258 "**Sublicensee**" means a Licensee Sublicensee or Relay Sublicensee.

1.259 "**Subsequent Clinical Trial-Related Contracts**" has the meaning set forth in Section 3.2.4(a).

1.260 "**Supply Agreement**" has the meaning set forth in Section 7.2.4.

1.261 "**Technology Transfer**" means the Development Transfer, the Manufacturing Transfer, the Regulatory Transfer and the Clinical Transfer.

1.262 "**Technology Transfer Plan**" means the technology transfer plan attached as Schedule 1.262.

1.263 "**Term**" has the meaning set forth in Section 16.1.

1.264 "**Terminated Other Licensed Product**" has the meaning set forth in Section 16.8.2(c).

1.265 "**Terminated Relay Pipeline Combination Eligible Licensed Product**" has the meaning set forth in Section 16.8.2(b).

1.266 "**Terminated Relay Pipeline Combination Eligible Licensed Product Terms**" has the meaning set forth in Section 16.8.2(b).

1.267 "**Termination Date**" has the meaning set forth in Section 16.8.1(a).

1.268 "**Territory**" means worldwide.

1.269 "**Third Party**" means any Person other than Relay or Licensee that is not an Affiliate of Relay or of Licensee. Notwithstanding anything in the foregoing of this Section 1.269, for purposes of this Agreement, [***].

1.270 "**Third Party Action**" has the meaning set forth in Section 12.11.1.

1.271 "**Third Party Claim**" means any suits, claims, actions, proceedings or demands brought by a Third Party.

1.272 "**Third Party Lead Product Action**" has the meaning set forth in Section 12.11.3.

1.273 "**Third Party Subcontractor**" means any Third Party service provider, consultant, CRO, CMO or subcontractor used by or on behalf of a Party or its Affiliates in the performance of activities under this Agreement.

1.274 "**Third Party Subcontractor Agreement**" means an agreement entered into by a Party with a Third Party Subcontractor.

1.275 "**TLF**" has the meaning set forth in Section 4.1.2.

1.276 "**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo or business symbol, whether or not registered.

1.277 "**Transfer of Sponsor Obligations**" has the meaning set forth in Section 3.2.3(b).

1.278 "**Transition Period**" has the meaning set forth in Section 16.9.3.

1.279 "**United States**" or "**U.S.**" means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.280 "**Valid Claim**" [***].

1.281 "**Violation**" with respect to a Person means that such Person is: (a) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of

Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (http://oig.hhs.gov/exclusions/authorities.asp); (b) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (http://exclusions.oig.hhs.gov/) or otherwise excluded from contracting with the federal government (see the System for Award Management (formerly known as the Excluded Parties Listing System) at http://sam.gov/portal/public/SAM/); or (c) listed by any U.S. federal agency as being suspended, debarred, disqualified, excluded or otherwise ineligible to participate in federal procurement or non-procurement programs, including under 21 U.S.C. 335a.

ARTICLE 2.
COLLABORATION OVERVIEW

2.1 Collaboration Overview. Prior to the Effective Date, Relay has been engaged in the Development of the Lead Candidate and Lead Products in the Field in the Territory. Under this Agreement, Relay and Licensee will collaborate in the further Development and Commercialization of the Lead Candidate and Lead Products in the Field in the Territory, and, subject to certain retained rights, to the extent set forth in Section 12.1, Relay grants Licensee an exclusive license for the Research, Development, Manufacture and Commercialization of Licensed Candidates and Licensed Products in the Field in the Territory. As part of the collaboration, (a) Relay will complete the Relay Phase Ia Trial in accordance with the Relay Phase Ia Plan and the applicable provisions of this Agreement, (b) Relay may share in the Development Costs and Net Profits and Net Losses for Shared Products with respect to the Profit Share Territory, and (c) Relay may Develop Relay Pipeline Combination Eligible Licensed Products solely in connection with the Development of Relay Pipeline Combinations and may co-promote the Relay Pipeline Combination Eligible Licensed Products solely for Combination Use in Relay Pipeline Combinations in coordination with Licensee and in accordance with this Agreement any applicable Coordinated Promotion Agreement. Except for the limited rights reserved to Relay hereunder, Licensee will have the sole right and responsibility to conduct Research and Development for the Licensed Candidates and Licensed Products and to Manufacture and Commercialize the Licensed Candidates and Licensed Products.

ARTICLE 3.
DEVELOPMENT

3.1 Generally. Except as otherwise expressly provided in this Article 3, Licensee shall have the sole right and responsibility to Develop the Licensed Candidates and Licensed Products in the Field in the Territory in its sole discretion.

3.2 Technology Transfer.

3.2.1 Development Transfer.

(a) Subject to clauses (b) and (c) of this Section 3.2.1, as promptly as possible and in any event in accordance with the timing set forth in the Technology Transfer Plan, Relay will, at its own cost and expense, initiate and complete a technology transfer to Licensee of the Relay Know-How, documentation and other Materials that relate to the Research, Development or Commercialization of the Lead Candidate or Lead Product (such Know-How,

documentation and Materials, the "**Development Know-How and Materials**") and that are listed on the Technology Transfer Plan (such transfer, the "**Development Transfer**"). To the extent any copies of documents or materials within the Development Know-How and Materials are in possession of a Third Party, Relay is solely responsible, at its own cost and expense, to procure and provide to Licensee all such Development Know-How and Materials, together with all rights to access and use any such Development Know-How and Materials in accordance with this Agreement (which may be procured or provided by letters of authorization or comparable instruments where approved by Licensee). Relay will make available its personnel (and use Commercially Reasonable Efforts to cause its Third Party Subcontractors with relevant subject matter expertise to be available) on a reasonable basis to consult with Licensee with respect to the Development Know-How and Materials and Development Transfer.

(b) It is understood and agreed that there may be additional Development Know-How and Materials that are not identified at the time of the Development Transfer but that are thereafter identified. If after the Development Transfer, either Party identifies any such additional Development Know-How and Materials that are in Relay's Control, Relay shall transfer such additional Know-How and Materials to Licensee promptly after such identification and notification.

(c) It is also understood and agreed that there are additional Development Know-How and Materials that are not yet existing at the time of the Development Transfer but are expected to be generated by Relay after the Effective Date. Relay shall provide such additional Development Know-How and Materials as such Know-How and Materials are generated, either in accordance with the timeline as set forth in the Technology Transfer Plan or in reasonable batches, as discussed by the Parties. [***].

3.2.2 Manufacturing Transfer.

(a) Subject to the remainder of this Section 3.2.2, as promptly as possible and in any event in accordance with the timing set forth in the Technology Transfer Plan, Relay will initiate and complete (and if applicable, use Commercially Reasonable Efforts to cause its CMO to initiate and complete) a technology transfer to Licensee, or to its CMO of the Phase Ia Product, such CMO to be selected by Licensee and reasonably acceptable to Relay, of Relay Know-How, documentation and other Materials that relate to the Manufacture of the Lead Candidate or Lead Product (such Know-How, documentation and Materials, the "**Manufacturing Know-How and Materials**") and that are listed on the Technology Transfer Plan (such transfer, the "**Manufacturing Transfer**"). To the extent any copies of documents or materials within the Manufacturing Know-How and Materials are in possession of a Third Party, Relay is solely responsible, at its own cost and expense, to procure and provide to Licensee all such Manufacturing Know-How and Materials, together with all rights to access and use any such Development Know-How and Materials in accordance with this Agreement (which may be procured or provided by letters of authorization or comparable instruments where approved by Licensee). Relay will make available its personnel and use Commercially Reasonable Efforts to cause its CMO and other Third Party Subcontractors with relevant subject matter expertise to be available on a reasonable basis to consult with Licensee or Licensee's CMO with respect to the Manufacturing Know-How and Materials and the Manufacturing Transfer. Relay will not be required to perform a Manufacturing Transfer to more than one CMO of Licensee. Subject to the completion of the Manufacturing

Transfer, Licensee will be solely responsible for contracting with its CMO for the supply of the Licensed Candidates or Licensed Products, and Relay will have no obligations under such agreement between Licensee and such CMO.

(b) It is understood and agreed that there may be additional Manufacturing Know-How and Materials that are not identified at the time of the Manufacturing Transfer and are thereafter identified. If after the Manufacturing Transfer, either Party identifies any such additional Know-How and Materials such Party shall notify the other Party, and if such Manufacturing Know-How and Materials are in Relay's Control, Relay shall transfer such additional Know-How and Materials to Licensee promptly after such identification and notification.

(c) To the extent any additional Manufacturing Know-How and Materials are generated by Relay after the Effective Date, Relay shall identify such Know-How and Materials and shall thereafter transfer such additional Know-How and Materials in reasonable batches as discussed by the Parties.

3.2.3 Regulatory Transfer.

(a) Relay shall (i) as promptly as possible and in any event in accordance with the timing set forth in the Technology Transfer Plan, provide all Regulatory Materials that relate to the Lead Candidate and Lead Product and (ii) promptly after the Effective Date use Commercially Reasonable Efforts to expeditiously transfer and assign to Licensee Relay's entire right, title, and interest in and to the IND for the Lead Product in the Relay Phase Ia Trial (the "**Relay IND**" and such transfer, the "**Relay IND Transfer**") ((i) and (ii) collectively, the "**Regulatory Transfer**"). The Regulatory Transfer will be conducted in accordance with the requirements of the Technology Transfer Plan, including the timing, method and format requirements set forth thereon. Relay will make available its personnel (and use Commercially Reasonable Efforts to cause its Third Party Subcontractors with relevant subject matter expertise to be available) on a reasonable basis to consult with Licensee with respect to the Regulatory Transfer.

(b) As part of the Regulatory Transfer, Relay shall (i) duly execute and send to the FDA (with confirmed receipt) a letter transferring ownership of the Relay IND and designation as the sponsor for such Relay IND to Licensee, including an update to the Sponsor obligations as set forth in Schedule 3.2.3 attached hereto (the "**Transfer of Sponsor Obligations**") executed by Relay, Licensee and the Relay Phase Ia Trial CRO, and deliver to Licensee copies thereof and (ii) execute or agree upon any necessary agreements (pursuant to Section 3.3.8 or 3.3.9) or amend any existing agreements (pursuant to Section 3.3.7), as necessary as part of such Relay IND Transfer. All such activities are a condition to completion of the Relay IND Transfer.

(c) It is understood and agreed that there may be additional Regulatory Materials that are not identified at the time of the Regulatory Transfer but which are thereafter identified and are necessary or reasonably useful for the Regulatory Transfer. If, after the Regulatory Transfer, either Party identifies any additional Regulatory Materials with respect to the Lead Candidate or Lead Products in the Field in the Territory, such Party shall notify the other Party, and if such additional Regulatory Materials are in Relay's Control and possession, then

Relay shall transfer such additional Regulatory Materials to Licensee promptly after such identification and notification.

(d) To the extent any additional Regulatory Materials are generated by Relay after the Effective Date, and to the extent providing such Regulatory Materials are not covered under the SAE Management Plan or elsewhere in this Agreement, Relay shall identify such Regulatory Materials and shall thereafter transfer such Regulatory Materials in reasonable batches as discussed by the Parties.

3.2.4 Clinical Transfer. Promptly after the Effective Date and in accordance with the timing set forth in the Technology Transfer Plan, Relay shall conduct the following activities (the transfer pursuant to this Section 3.2.4, the "**Clinical Transfer**"):

(a) Relay shall cooperate with and assist Licensee by identifying key Third Party Subcontractors and any agreements entered into by Relay with such key Third Party Subcontractors to prepare for a subsequent Clinical Trial by Licensee for the Lead Candidate or Lead Products, including CRO agreements, clinical trial agreements, institutional review board agreements, manufacturing agreements, supply agreements, laboratory services agreements, and other service provider agreements ("**Subsequent Clinical Trial-Related Contracts**"). At Licensee's reasonable request, Relay shall use Commercially Reasonable Efforts to assign and transfer its rights and obligations under any Subsequent Clinical Trial-Related Contract with respect to the Lead Candidate or Lead Products to Licensee; provided, however, that Licensee shall inform Relay which Subsequent Clinical Trial-Related Contracts are to be assigned. To the extent such assignment and transfer is either not practicable, or not requested, Relay shall cooperate with and assist Licensee, at Licensee's reasonable request, in coordinating the transition of such rights and obligations (or proposed rights and obligations) from Relay to Licensee with such Third Parties (including providing relevant contact information and making introductions to key personnel of such Third Parties);

(b) Upon receipt of the Inventory at the location designated by Licensee, Relay hereby sells, conveys assigns and transfers to Licensee all right, title and interest in and to the Inventory. Relay shall enter into customary documents, including an appropriate bill of sale, if required, for shipment of Inventory to Licensee. [***]. Relay shall deliver, or authorize Licensee to direct the relevant Third Party Subcontractor to deliver, to Licensee Inventory required to be shipped to Licensee pursuant to this Section 3.2.4(b) to the location designated by Licensee using a carrier selected by and paid for by Licensee, DAP(Incoterms 2020); and

(c) Relay shall coordinate and cooperate with Licensee to transfer to Licensee the data and information relating to the Relay Phase Ia Trial (the "**Relay Phase Ia Trial Data**"). To the extent any Relay Phase Ia Trial Data is in the possession of a Third Party, Relay shall deliver any necessary instruments, including any letters of authorization and transfer of ownership, to such Third Party to grant Licensee the right to have transferred such Relay Phase Ia Trial Data from such Third Party and to document and to transfer any such Relay Phase Ia Trial Data from Relay to Licensee.

(d) For ongoing ancillary studies (chronic tox, stability, etc.) supporting the Relay Phase Ia Trial or necessary to maintain the IND for the Lead Product, upon Licensee's

request Relay will transfer any such study to Licensee (or, as requested by Licensee, enter into an arrangement that delegates the roles, rights, and responsibilities for such study between Licensee, Relay and the Third Party Subcontractor supporting such study, including without limitation taking actions substantially similar to those described in Section 3.3.7 for such study) and all data and information relating to such studies.

(e) Relay will make available its personnel (and use Commercially Reasonable Efforts to cause its Third Party Subcontractors with relevant subject matter expertise to be available) on a reasonable basis to consult with Licensee with respect to the Clinical Transfer. It is understood and agreed that there may be additional data and information relevant to the Clinical Transfer that are not identified at the time of the Clinical Transfer but are necessary or reasonably useful for the Development of the Lead Candidate or Lead Product and are thereafter identified. If after the Clinical Transfer, either Party identifies any such additional data and information such Party shall notify the other Party, and if such data and information are in Relay's Control, then Relay shall transfer such additional data and information to Licensee promptly after such identification and notification.

3.2.5 Technology Transfer Plan. The Technology Transfer will be conducted in accordance with the Technology Transfer Plan, including the timing, method and format requirements set forth therein.

3.3 Relay Phase Ia Trial Prior to the Relay IND Transfer Date. This Section 3.3 will apply from the Effective Date until the Relay IND Transfer Date and thereafter Section 3.4 shall apply.

3.3.1 Generally. Until completion of the Relay IND Transfer, Relay will remain responsible as Sponsor for the Relay Phase Ia Trial and will conduct the Relay Phase Ia Trial in accordance with a written development plan that includes a description of Relay's activities for the Relay Phase Ia Trial, which may be amended in accordance with this Section 3.3 or Section 3.4, as applicable (the "**Relay Phase Ia Plan**") and in compliance with Applicable Laws, including maintaining a global safety database for safety and risk management activities as required by Applicable Laws. A copy of the initial Relay Phase Ia Plan is attached hereto as Schedule 3.3. In the event of any inconsistency between the Relay Phase Ia Plan and this Agreement, the terms of this Agreement will prevail.

3.3.2 Amendments, Changes and Approvals. Either Party (through its representatives on the JDT after the JDT is formed), may propose amendments to the Relay Phase Ia Plan at any time until such time as no further Development activities are occurring or expected to occur under such Relay Phase Ia Plan. No amendment or material change to the Relay Phase Ia Plan, including any change to the protocol or investigator's brochure, will be effective unless and until approved by the JDT. Notwithstanding the foregoing, in the event Licensee desires to amend the Relay Phase Ia Plan to add an additional clinical or non-clinical study to the Relay Phase Ia Plan that is not required nor requested by a Regulatory Authority (each, an "**Optional Additional Phase Ia Study**"), then Licensee will submit the Optional Additional Phase Ia Study to Relay (through the JDT after the JDT is formed) for consideration. If Relay agrees to the addition of the Optional Additional Phase Ia Study to the Relay Phase Ia Plan, then the Relay Phase Ia Plan will be amended to add such Optional Additional Phase Ia Study at Licensee's cost. If Relay does not

agree to the addition of the Optional Additional Phase Ia Study to the Relay Phase Ia Plan, then Licensee may conduct such Optional Additional Phase Ia Study at its own expense outside of the Relay Phase Ia Plan. If during the conduct of the Relay Phase Ia Trial a Regulatory Authority requires that an additional clinical or non-clinical study be conducted or otherwise requires an amendment to the protocol for the Relay Phase Ia Trial (a "**Required Additional Phase Ia Study**"), then the Parties will amend the Relay Phase Ia Plan to add such Required Additional Phase Ia Study [***]. If during the conduct of the Relay Phase Ia Trial a Regulatory Authority requests but does not require an additional clinical or non-clinical study be conducted or otherwise requests but does not require an amendment to the protocol for the Relay Phase Ia Trial (a "**Requested Additional Phase Ia Study**"), the Parties will, through the JDT, discuss in good faith whether the Requested Additional Phase Ia Study can and should be conducted as part of and with the same patient population as the existing or planned Relay Phase Ia Trial, or whether it should be conducted as a separate study by Licensee, taking into consideration strategic factors and timing and resource considerations. [***]. It is understood that time is of the essence in Relay's ability to conduct the Relay Phase Ia Plan, and that no decisions of the JDT shall be unreasonably withheld or delayed.

3.3.3 Conflicting Activities. Licensee shall have the right (through the JDT after the JDT is formed), to review and provide comments on Development activities with respect to the Relay Phase Ia Trial and to withhold approval of any Development activities that may, in Licensee's good faith belief, conflict with, or have a negative impact on, Licensee's Development activities with respect to Licensed Candidates or Licensed Products (including Licensee's activities under the Global Development Plan during an Opt-In Term). Development activities that are conducted in accordance with the Relay Phase Ia Plan are hereby deemed by the Parties to not be in conflict with, and to not have a negative impact on, Licensee's Development activities with respect to Licensed Candidates or Licensed Products. Notwithstanding the foregoing, if (a) prior to the transfer to Licensee of the safety database for the Relay Phase Ia Trial a (i) DLT or (ii) SAE, in each case ((i) and (ii)) that is related or could potentially be related to the Licensed Candidate or Licensed Product, or (b) following the transfer to Licensee of the safety database for the Relay Phase Ia Trial any DLT or SAE, is observed in the conduct of Development activities under this Agreement, then the Parties shall meet immediately to discuss next steps and, if Licensee then in good faith determines that any Development activities contemplated in the then-current Relay Phase Ia Plan would conflict with, or have a negative impact on, the safety of the Licensed Candidates or Licensed Product, Licensee shall have the right to prohibit Relay from conducting such activities and the Parties will modify the Relay Phase Ia Plan and such activities as reasonably directed by Licensee to address such safety concerns. To the extent Relay's conduct then conforms to such modified activities in accordance with the modified Relay Phase Ia Plan, then such conduct will be deemed to not be in conflict with, and to not have a negative impact on, Licensee's Development activities with respect to Licensed Candidates or Licensed Products. Further, notwithstanding anything herein to the contrary, nothing in this Section 3.3.3, shall limit Relay's ability to comply with Applicable Laws or to act in the interest of the safety of subjects participating in any Clinical Trials.

3.3.4 Information Sharing; Decision Making. Until completion of the Relay IND Transfer Date, Relay will provide updates regarding its Development activities with respect to the Relay Phase Ia Trial and comply with Section 3.9.1, and will provide such other information with respect to the Relay Phase Ia Trial as is reasonably requested by Licensee and is in Relay's Control.

Relay will also provide notice to Licensee and the opportunity to review and approve any decision for which Licensee has final decision making rights with respect to the Relay Phase Ia Trial under Section 10.7.3(b).

3.3.5 Regulatory Rights and Responsibilities. The Parties will have the rights and responsibilities set forth in Section 6.3.1.

3.3.6 Subcontractor Meetings. Relay will provide Licensee with reasonable advance notice of all meetings with the Relay Phase Ia Trial CRO, Relay's CMO and Relay's other Third Party Subcontractors (including investigators) pertaining to the Relay Phase Ia Trial, and use Commercially Reasonable Efforts to coordinate scheduling of such meetings to enable Licensee to participate in all such meetings, including any meetings relating to dose or safety, and Licensee shall have final say on any decisions as provided in Section 10.7.3(b), regardless of whether the JDT has yet been formed.

3.3.7 Amendments to CRO and CMO Agreements. As soon as practicable after the Effective Date, Relay will, as may be necessary or desirable, negotiate in good faith and enter into amendments to its existing agreements, letters of authorization, side letters, written confirmation or any other binding and written agreements with the Relay Phase Ia Trial CRO and its CMO and other Third Party Subcontractors for the Relay Phase Ia Trial to ensure that (a) Licensee will have the right to carry out the responsibilities assigned to it under the Delegation of Authority, SAE Management Plan and Quality Agreement and (b) such agreements are consistent with and enable Licensee to exercise its rights under such documents and this Agreement. Licensee will reasonably cooperate with such negotiations, including negotiating in good faith and entering into an acceptable three-party agreement with Relay and the Relay Phase Ia Trial CRO, CMO or other Third Party Subcontractor, as applicable, to the extent necessary or reasonably requested by Relay. Relay agrees to use Commercially Reasonable Efforts to complete the foregoing actions prior to the anticipated Relay IND Transfer Date, and acknowledges that they are conditions to completion of the Relay IND Transfer.

3.3.8 Safety and Serious Adverse Event Management Plan. Prior to the Relay IND Transfer Date, the Parties will, and will use Commercially Reasonable Efforts to cause the Relay Phase Ia Trial CRO and other Third Party Subcontractors, as applicable, to, negotiate in good faith and enter into a pharmacovigilance agreement or SAE management plan (the "**SAE Management Plan**"), that will govern the transfer of the safety database (which shall occur simultaneously or promptly upon execution of the SAE Management Plan), exchange of safety data information, adverse events reporting and Licensed Product complaints with respect to the Relay Phase Ia Trial to ensure timely communication to Regulatory Authorities and compliance with Applicable Law and to designate rights and responsibilities as between such parties to support the Relay IND after the Relay IND Transfer Date. Relay acknowledges that the transfer of the safety database and execution of the SAE Management Plan are conditions to completion of the Relay IND Transfer. Prior to the transfer of any activities by Relay to a Relay Combination Collaborator, the Parties will enter into a three (3) party pharmacovigilance agreement with such Relay Combination Collaborator.

3.3.9 Quality Agreement. Prior to the Relay IND Transfer Date, the Parties will, and will use Commercially Reasonable Efforts to cause Relay's CMO for the Relay Phase Ia Trial

to, negotiate in good faith and enter into a quality agreement (the "**Quality Agreement**") with respect to the supply of Phase Ia Product for the Relay Phase Ia Trial and to designate rights and responsibilities as between such parties to support the IND for the Relay Phase Ia Trial after the Relay IND Transfer Date. Relay acknowledges that the foregoing is a condition to completion of the Relay IND Transfer.

3.4 Relay Phase Ia Trial after the Relay IND Transfer Date. This Section 3.4 will apply after the Relay IND Transfer Date.

3.4.1 Generally. Relay will continue to conduct the Relay Phase Ia Trial in accordance with the Relay Phase Ia Plan and in compliance with all Applicable Laws, provided that Licensee will be responsible as Sponsor for the Relay Phase Ia Trial and Relay will provide reasonable assistance and support to Licensee as Sponsor of the Relay Phase Ia Trial to maintain the Relay IND as described further in this Section 3.4. Without limiting any other provision herein, Licensee, Relay, the Relay Phase Ia Trial CRO and Relay's CMO and other Third Party Subcontractors for the Relay Phase Ia Trial, as applicable, will have the respective rights and responsibilities with respect to the Relay Phase Ia Trial assigned to them in the Delegation of Authority attached as Schedule 3.4.1("**Delegation of Authority**"), the SAE Management Plan and the Quality Agreement. The Parties agree to update the Delegation of Authority upon finalization of the SAE Management Plan if necessary in order to conform such Delegation of Authority to the SAE Management Plan.

3.4.2 Amendments, Changes and Approvals. Either Party (through its representatives on the JDT after the JDT is formed) may propose amendments to the Relay Phase Ia Plan at any time until such time as no further Development activities are occurring or expected to occur under such Relay Phase Ia Plan. No amendment or material change to the Relay Phase Ia Plan, including any change to the protocol or investigator's brochure, will be effective unless and until approved by Licensee. Notwithstanding the foregoing, in the event Licensee desires to amend the Relay Phase Ia Plan to add an Optional Additional Phase Ia Study, then Licensee will submit the Optional Additional Phase Ia Study to Relay (through the JDT after the JDT is formed) for consideration before making such amendment. If Relay agrees to the addition of the Optional Additional Phase Ia Study to the Relay Phase Ia Plan, then the Relay Phase Ia Plan will be amended to add such Optional Additional Phase Ia Study. If Relay does not agree to the addition of the Optional Additional Phase Ia Study to the Relay Phase Ia Plan, then Licensee may conduct such Optional Additional Phase Ia Study at its own expense outside of the Relay Phase Ia Plan. [***]. With respect to a Requested Additional Phase Ia Study the Parties will, through the JDT, discuss in good faith whether the Requested Additional Phase Ia Study can and should be conducted as part of and with the same patient population as the existing or planned Relay Phase Ia Trial, or whether it should be conducted as a separate study by Licensee, taking into consideration strategic factors and timing and resource considerations. [***]. It is understood that time is of the essence in Relay's ability to conduct the Relay Phase Ia Plan, and that no decisions of the JDT shall be unreasonably withheld or delayed.

3.4.3 Conflicting Activities. Licensee shall have the right (through the JDT after the JDT is formed), to review and provide comments on Development activities with respect to the Relay Phase Ia Trial and to withhold approval of any Development activities that may, in Licensee's good faith belief, conflict with, or have a negative impact on, Licensee's Development

activities with respect to Licensed Candidates or Licensed Products (including Licensee's activities under the Global Development Plan during an Opt-In Term). Development activities that are conducted in accordance with the Relay Phase Ia Plan are hereby deemed by the Parties to not be in conflict with, and to not have a negative impact on, Licensee's Development activities with respect to Licensed Candidates or Licensed Products. Notwithstanding the foregoing, if a (a) DLT or (b) SAE is observed in the performance of Development activities hereunder, the Parties shall meet immediately to discuss next steps and, if Licensee then in good faith determines that any Development activities contemplated in the then-current Relay Phase Ia Plan would conflict with, or have a negative impact on, the safety of the Licensed Candidates or Licensed Product, Licensee shall have the right to prohibit Relay from such activities and the Parties will modify the Relay Phase Ia Plan and such activities as directed by Licensee to address such safety concerns. To the extent Relay's conduct then conforms to such modified activities in accordance with the modified Relay Phase Ia Plan, then such conduct will be deemed to not be in conflict with, and to not have a negative impact on, Licensee's Development activities with respect to Licensed Candidates or Licensed Products. The approval rights set forth in this Section 3.4.2 shall not limit Licensee's approval rights pursuant to the Delegation of Authority, SAE Management Plan or Quality Agreement. Further, notwithstanding anything herein to the contrary, nothing in this Section 3.4.2, shall limit Relay's ability to comply with Applicable Laws or to act in the interest of the safety of subjects participating in any Clinical Trials.

3.4.4 Information Sharing; Decision Making. After the Relay IND Transfer Date, Relay will provide updates regarding its Development activities with respect to the Relay Phase Ia Trial and comply with Section 3.9.1, and will provide such other information with respect to the Relay Phase Ia Trial as is reasonably requested by Licensee and is in Relay's Control. If Licensee is conducting Clinical Trials of the Lead Product during the time period that Relay is conducting the Relay Phase Ia Trial, Licensee will provide material updates to Relay regarding Licensee's Development activities, and will provide such other material information as is reasonably requested by Relay, and notice of DLT and SAEs, as provided in Section 3.9.1, *mutatis mutandis*. Relay will also provide notice to Licensee and the opportunity to review and approve any decision for which Licensee has final decision making rights with respect to the Relay Phase Ia Trial under Section 10.7.3(b).

3.4.5 Regulatory Rights and Responsibilities. The Parties will have the rights and responsibilities set forth in Section 6.3.2.

3.4.6 Subcontractor Meetings. Relay will provide Licensee with reasonable advance notice of all meetings with the Relay Phase Ia Trial CRO, Relay's CMO and Relay's other Third Party Subcontractors (including investigators) pertaining to the Relay Phase Ia Trial, and use Commercially Reasonable Efforts to coordinate the schedules of the Parties to enable Licensee to participate in all such meetings, and Licensee shall have final say on any decisions as provided in Section 10.7.3(b).

3.4.7 Transfer of Phase Ia Trial. Anytime after the Relay IND Transfer Date, notwithstanding anything in the foregoing, if Licensee may request by written notice to Relay that the conduct of the Relay Phase Ia Trial be transferred to Licensee, in whole or in part, such that Licensee has the sole right and responsibility for the conduct of such transferred Relay Phase Ia Trial. If Licensee request to transfer the Relay Phase Ia Trial in whole based upon a breach by

Relay of any of its obligations in Sections 3.2, 3.3, 3.4, 3.9.1, 6.3 and 6.4 that remains uncured [***] after written notice thereof from Licensee to Relay or multiple [***] breaches of such provisions which were previously notified by Licensee to Relay, whether or not cured or curable, then such notice will describe such uncured breach or multiple prior breaches in reasonable detail, including identifying the provisions breached, and will state Licensee's intention to transfer the Relay Phase Ia Trial pursuant to this Section 3.4.7. Upon receipt of written notice pursuant to this Section 3.4.7, Relay shall transfer the conduct of the Relay Phase Ia Trial (or the applicable part thereof) to Licensee as reasonably directed in an expeditious manner. For avoidance of any doubt, the cost sharing provisions set forth in this Section 3.4 shall not be changed as a result of such transfer.

3.5 Global Development Plan. In the event Relay exercises its Opt-In Right, then this Section 3.5 will apply during the Opt-In Term.

3.5.1 Global Development Plan. Except with respect to Relay's obligations under Section 3.3 and 3.4, Licensee will use Commercially Reasonable Efforts to Develop the Lead Products in the Field in the Territory in accordance with the Global Development Plan, subject to any amendments to the Global Development Plan, which will be subject to JDT approval in accordance with Section 10.2.2(g). For clarity, Licensee may at its option Develop any such [***] Combination outside of the Global Development Plan, provided that the foregoing shall not limit the Parties rights and obligations with respect to sharing of Net Profits and Net Losses during the Opt-In Term as provided hereunder. In the event of any inconsistency between the Global Development Plan and this Agreement, the terms of this Agreement will prevail.

3.5.2 Global Development Budget. The Global Development Plan will contain the Global Development Budget. The first full Calendar Year of the then-current Global Development Budget, will be binding for purposes of calculating First Tier GDP Overruns and Second Tier GDP Overruns as provided in Section 3.8.5, and will be non-binding for all other purposes. The Global Development Budget, and each update thereto, will be prepared by Licensee based on Licensee's good faith estimation, consistent with its standard internal practices, of the probable Development activities to be conducted during the relevant Global Development Budget period, and based on and consistent with the documents and information related to the Licensed Products prepared by Licensee for its internal use and reference in the budgeting process. Upon request by Relay, the JDT will discuss the appropriate level of detail to include in the Global Development Budget for the applicable Development activities to be performed during the period covered by such Global Development Budget.

3.5.3 Reviews. Beginning with the first [***] of the Opt-In Term and for each year thereafter during the Opt-In Term until such time as no further Development activities are occurring or expected to occur under such Global Development Plan, Licensee will provide to the JDT, [***], any updates to the Global Development Plan proposed for the following Calendar Year and thereafter, and thereupon, the JDT will review and discuss such updated GDP and endeavor to approve such updated GDP within [***] after receipt of such updated GDP.

3.5.4 Updates. The Global Development Budget included in the updated GDP provided in accordance with Section 3.5.3 will contain [***], in accordance with the requirements set forth in Section 3.5.2.

3.5.5 Amendments. In addition to the annual updates, either Party, through its representatives on the JDT, may propose amendments to the Global Development Plan at any time until such time as no further Development activities are occurring or expected to occur under such Global Development Plan, including amendments to add Development activities to such Global Development Plan.

3.5.6 Approvals. No annual update or amendment to the Global Development Plan will be effective unless and until approved by the JDT.

3.6 Diligence. Relay will use Commercially Reasonable Efforts to perform the Development activities set forth in the Relay Phase Ia Trial in accordance with the Relay Phase Ia Plan and in accordance with the estimated timetables set forth therein and to perform its obligations under Sections 6.3 and 6.4, including dedicating the appropriate amount of time and personnel in terms of knowledge and expertise to support the conduct of the Relay Phase Ia Trial and the Relay IND hereunder in the following functional areas: [***]. Licensee will use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval for and launch at least [***] Licensed Product in the Field in [***]. The GDP as of the Effective Date prioritizes a [***] Combination with the Lead Product [***], and for avoidance of any doubt, Licensee reserves the right to reprioritize based on the factors that are contemplated while using Commercially Reasonable Efforts. For the avoidance of doubt, (a) [***] and (b) the exercise of diligence by Licensee with respect to a Licensed Product is to be determined by judging Licensee's Commercially Reasonable Efforts with respect to such Licensed Product taken as a whole.

3.7 Relay Pipeline Combinations.

3.7.1 Notwithstanding anything herein to the contrary, Relay and its Affiliates retain the right to Develop all Relay Pipeline Combination Eligible Licensed Products solely for Combination Use in Relay Pipeline Combinations. The Development of Relay Pipeline Combinations will occur separate from Licensee's Development activities with respect to the Licensed Products and Licensed Candidates, subject to Section 3.7.2.

3.7.2 Prior to conducting any Development activities with respect to a Relay Pipeline Combination, Relay will submit a proposed plan for such activities to the JDT, including if applicable a summary development plan for Regulatory Approval of such Relay Pipeline Combination (the "**Proposed Relay Pipeline Combination Development Plan**"). Within [***] days following the submission of such proposed plan to the JDT, Licensee will respond to Relay in writing indicating whether Licensee reasonably expects that the proposed Development activities with respect to a Relay Pipeline Combination in the Proposed Relay Pipeline Combination Development Plan will materially conflict with or negatively impact Licensee's Development activities with respect to Licensed Products and Licensed Candidates (including Licensee's activities under the Global Development Plan during an Opt-In Term), including a list of any expected conflicts or negative impacts (such as safety) and the reasons therefor. The Parties will discuss and attempt to resolve in good faith such issues, including considering whether Relay's Development activities can be modified to avoid any conflicts or negative impacts. If the Parties do not agree on modifications to address Licensee's concerns, Relay may proceed with such activities, subject to Licensee's final say to stop such activities as provided in Section 10.7.3(b), Licensee's approval rights in the Delegation of Authority, SAE Management Plan, and Quality

Agreement; provided that Licensee's approval shall be required for Relay to proceed with respect to such activities that would conflict with, or have a negative impact on, Licensee's Development activities under the GDP. In no event shall a delay in response by Licensee be taken to be deemed as an indication that there is no such conflict or negative impact. If after submission of the Proposed Relay Pipeline Combination Development Plan to the JDT, Relay proposes to make any changes to the Proposed Relay Pipeline Combination Development Plan that could reasonably be expected to materially conflict with or negatively impact Licensee's Development activities with respect to Licensed Products and Licensed Candidates, Relay will submit such changes to the JDT and this Section 3.7.2 will apply to such proposed changes (*mutatis mutandis*).

3.8 Development Costs and Launch Costs.

3.8.1 Relay Phase Ia Trial. Except as set forth in Sections 3.3.2 and 3.4.2, (a) Relay will be responsible for [***] up to the Relay IND Transfer Date, (b) after the Relay IND Transfer Date, [***], and (c) otherwise each Party shall bear its own costs and expenses in performing its responsibilities and activities with respect to the Relay Phase Ia Trial.

3.8.2 Relay Pipeline Combinations. Relay will be responsible for [***] for each Relay Pipeline Combination except that Licensee will provide the Relay Pipeline Combination Eligible Licensed Product therefor to Relay [***], Licensee will [***] for such Relay Pipeline Combinations in accordance with either (a) or (b) below (with such [***] being determined in the same manner as [***] pursuant to Section [***], *mutatis mutandis*: [***].

For avoidance of any doubt, if Licensee does not elect the [***] with respect to a Relay Pipeline Combination and such Relay Pipeline Combination does not receive Regulatory Approval in the Profit Share Territory, Licensee will not be required to [***] with respect to such Relay Pipeline Combination. As used in this Section 3.8.2, "**Global Trial**" shall mean, with respect to any Relay Pipeline Combination, [***]

3.8.3 Payment Elections.

(a) Promptly following preparation and compilation of the final approved tables, listings and figures for the Clinical Trial for a Relay Pipeline Combination immediately preceding [***] Pivotal Trial for such Relay Pipeline Combination, Relay will provide Licensee the same, together with the total development cost incurred or accrued for Global Trials of such Relay Pipeline Combination through such date, and a proposed clinical development plan and budget for the Pivotal Trial, including trial design, protocol, patient and site selection (the "**Licensee Selection Data Package**") to Licensee. If the Licensee Selection Data Package provided by Relay is incomplete, then Licensee may notify Relay of the incomplete status of such Licensee Selection Data Package in writing including any items that, in Licensee's reasonable determination made in good faith, should have been included therein but were not included therein within [***] after receipt thereof. Following receipt of such notice, to the extent such missing data is available, Relay will promptly deliver to Licensee the additional information to complete the Licensee Selection Data Package.

(b) Licensee will have the right to [***] of the Relay Pipeline Combination in accordance with Section 3.8.2(a) by providing with written notice thereof within

[***] after receipt of the complete Licensee Selection Data Package (such time period, the "**Licensee Selection Data Package Review Period**", and election of such funding, the "**Early Payment Election**"). For the avoidance of doubt, the Licensee Selection Data Package Review Period will not commence until Licensee has been provided a complete Licensee Selection Data Package.

(c) If Licensee does not elect the [***] and the Relay Pipeline Combination receives Regulatory Approval in the Profit Share Territory, Relay will thereafter [***] pursuant to Section [***] in accordance with Section[***] If Licensee elects the [***], Relay will thereafter [***] pursuant to sub-clause (i) of Section [***] in accordance with Section [***] and will Relay will [***] Licensee [***] pursuant to sub-clause [***] of Section [***] in the same manner as Licensee [***] to Relay for [***] pursuant to Section [***] *mutatis mutandis*.

3.8.4 Shared Products; Royalty Products.

(a) During the Opt-In Term, the Parties will share all Development Costs for Development activities conducted under the Global Development Plan for the Shared Products and all Launch Costs for the Shared Products, in each case in accordance with the applicable Sharing Percentages and in accordance with Section 11.3.1.

(b) Licensee will be responsible for all development costs for all Royalty Products (for the avoidance of doubt, however, excluding Relay's development costs relating to Licensed Products or Licensed Candidates in connection with Development of Relay Pipeline Combinations).

3.8.5 [***].

3.9 Reports; Records.

3.9.1 Commencing with the first meeting of the JDT and continuing until delivery of the TLF to Licensee pursuant to Section 4.1.2, Relay will prepare and deliver to the JDT, written reports summarizing its Development activities performed to date by Relay (or updating such report for activities performed since the last such report submitted hereunder, as applicable) with respect to the Relay Phase Ia Trial (including if (a) prior to the transfer to Licensee of the safety database for the Relay Phase Ia Trial, a (i) dose-limiting toxicity ("**DLT**") or (ii) serious adverse event ("**SAE**"), in each case ((i) and (ii)) that is related to or could reasonably be related to the Licensed Candidate or Licensed Product, is observed or (b) following the transfer to Licensee of the safety database for the Relay Phase Ia Trial any DLT or SAE is observed in the Relay Phase Ia Trial) at least [***] prior to each scheduled JDT meeting. Relay will further report to the JDT (and for the period prior to the formation of the JDT, directly to Licensee) (A) prior to implementation, any contemplated amendments or material changes to the Relay Phase Ia Plan and any contemplated Development activities with respect to a Relay Pipeline Combination that could reasonably be expected to materially conflict with or negatively impact the design or conduct of any Development activities contemplated by Licensee, including pursuant to the GDP, (B) if a (1) DLT or (2) SAE is observed in accordance with the SAE Management Plan, or prior to execution of the SAE Management Plan, is observed and is related to or could reasonably be related to the Licensed Candidate or Licensed Product, then immediately, and in any event within

[***] after observation of or becoming aware of such DLT or SAE event, (C) immediately (and in any event within [***]) whenever Relay receives an inquiry/request for information or other Material Communication from a Regulatory Authority with respect to the Relay Phase Ia Trial, (D) any contemplated dose or cohort decision with respect to the Relay Phase Ia Trial prior to any such decision, and (E) such other data and information and summaries thereof as are agreed by the JDT in the data and information sharing plan contemplated in Section 10.2.2(k).

3.9.2 For such period during which Relay is conducting Development activities for Relay Pipeline Combinations, at least [***] prior to each Calendar Quarter JDT meeting, Relay will prepare and deliver to the JDT, written reports summarizing Development activities for Relay Pipeline Combinations performed to date by Relay (or updating such report for activities performed since the last such report submitted hereunder, as applicable), including copies of study designs, protocols and results for Clinical Trials for each Relay Pipeline Combination. Relay will further promptly report to the JDT any regulatory communications related to the Licensed Candidates or Licensed Products, including the Clinical Trials conducted by Licensee in the Global Development Plan. Relay will report to Licensee (a) the observation of a (i) DLT or (ii) SAE in accordance with the Pharmacovigilance Agreement, or prior to execution of such Pharmacovigilance Agreement, immediately, and in any event within [***] after becoming aware of any (A) DLT or (B) SAE in each case ((A) and (B)) that is observed and is related to or could reasonably be related to the Licensed Candidate or Licensed Product, and (b) such other data and information and summaries thereof as are agreed by the JDT in the data and information sharing plan contemplated in Section 10.2.2(k).

3.9.3 For such period during the Opt-In Term as Licensee is conducting Development activities for Shared Products under the Global Development Plan, at least [***] prior to each Calendar Quarter JDT meeting, Licensee will prepare and deliver to the JDT, written reports summarizing Development activities for Shared Products performed to date by Licensee (or updating such report for activities performed since the last such report submitted hereunder, as applicable), including copies of study designs, protocols and results for Clinical Trials for each Shared Product.

3.9.4 For such period as Licensee is conducting Development activities for any Back-Up Compound or any Back-Up Product (or outside of the Opt-In Term, the Lead Candidate or any Lead Product) and any Back-Up Development/Commercial Milestones pursuant to Section 11.5.3 (or Development/Commercial Milestones pursuant to Section 11.5.1 outside of the Opt-In Term), in each case that are tied to Development activities, remain to be achieved, on or about [***] of each Calendar Year, Licensee will provide Relay with an annual written report summarizing the material Development activities undertaken by Licensee with respect to the Back-Up Compounds and Back-Up Products (and outside of the Opt-In Term, the Lead Candidate and Lead Products) in the immediately preceding Calendar Year. Such reporting with respect to any Back-Up Compound or Back-Up Product (and outside of the Opt-In Term, the Lead Candidate and any Lead Product), shall commence following the initiation of the first IND-enabling study of such Back-Up Compound or Back-Up Product (or the Lead Candidate or Lead Product, as applicable), until Development activities are no longer being conducted with respect to such Back-Up Compound or Back-Up Product (or the Lead Candidate or Lead Product, as applicable).

3.9.5 Each Party will provide the members of the JDT with written copies of all materials it intends to present at a JDT meeting. The JDT may also request at any time specific material data or information related to relevant Development activities or that a written report be prepared in advance of any meeting summarizing certain material data and information arising out of the conduct of relevant Development activities, and the Party or appropriate committee to whom such request is made will promptly provide to the other Party or JDT such report, data or information that was reasonably requested.

3.9.6 If during the Opt-In Term Licensee or its Affiliates makes a decision, including through a governance committee ([***] or their respective equivalent if such committees do not exist in the future), to permanently cease all Development and Commercialization activities with respect to a given Licensed Product, then Licensee will report such cessation and the date of such decision in the first report provided to Relay pursuant to Section 3.9.3 after such date.

3.9.7 If Relay or its Affiliates makes a decision to cease all Development and Commercialization activities with respect to a given Relay Pipeline Combination, then Relay will report such cessation and the date of such decision in the first report provided to Licensee pursuant to Section 3.9.2 after such date.

3.9.8 Each Party will maintain records with respect to the Lead Candidate, Back-Up Compounds, Lead Products and Back-Up Products (including Combination Use thereof), in sufficient detail and in sound scientific manner appropriate for Patent and regulatory purposes and in compliance with GLP, GMP and GCP, as applicable, with respect to activities intended to be submitted in regulatory filings (including INDs). All such records, and the information disclosed therein, are the Confidential Information of the Party maintaining such records and will be protected as Confidential Information by the recipient Party in accordance with Article 13.

OPT-IN RIGHT; OPT-OUT RIGHT

4.1 Opt-In Right.

4.1.1 Subject to the remainder of this Section 4.1, Licensee hereby grants to Relay an exclusive option, exercisable in Relay's sole discretion one (1) time, to fund Development Costs for Lead Products in the Field and share in the Net Profits and Net Losses of Commercializing Lead Products in the Field in the Profit Share Territory, such funding and sharing of Net Profits and Net Losses to be in accordance with the Sharing Percentages (collectively, the "**Opt-In Right**").

4.1.2 Promptly following preparation and compilation of the final tables, listings and figures from the Relay Phase Ia Trial (the "**TLF**"), Relay will provide the same to Licensee. Within [***] after Licensee's receipt of the TLF, Licensee will provide to Relay (a) a proposed, updated Global Development Plan, with the proposed updates thereto based in part on the TLF, other data and information created, conceived or generated in the conduct of the Relay Phase Ia Trial and on Licensee's then good-faith plans with respect to Development of Lead Products (which Relay acknowledges may not be complete, with respect to all Licensee Combination Agents included in the initial Global Development Plan), (b) a good faith estimate of Development

Costs incurred through such date for any Clinical Trials commenced by Licensee for Lead Products prior to such date (the "**Opt-In Data Package**"). Relay may exercise its Opt-In Right [***] following receipt of the Opt-In Data Package in accordance with this Section 4.1.2 (the "**Opt-In Deadline**"). For clarity, if Relay elects to exercise its Opt-In Right prior to receipt of the Opt-In Data Package (including the amended Global Development Plan contained therein), Relay shall have no right to revisit its election to exercise its Opt-In Right or object to the amended Global Development Plan, provided that [***] and (b) Relay shall have the right to exercise its Opt-Out Right as provided in Section 4.2.

4.1.3 If the TLF provided by Relay in accordance with Section 4.1.2 is incomplete, Licensee may notify Relay in writing of the incomplete status of such TLF in writing including any items that, in Licensee's reasonable determination made in good faith, should have been included therein but were not included therein within [***] after receipt thereof. Following receipt of such notice, Relay will promptly deliver to Licensee the additional information requested by Licensee to complete the TLF. For clarity, delivery of such incomplete TLF will not trigger the [***] period for Licensee to provide to Relay the Opt-In Data Package, but such [***] period will thereafter be triggered on the date of Licensee's receipt of the additional information requested by Licensee to complete the TLF.

4.1.4 If the Opt-In Data Package provided in accordance with Section 4.1.2 is incomplete, Relay may notify Licensee in writing of the incomplete status of such Opt-In Data Package in writing including any items that, in Relay's reasonable determination made in good faith, should have been included therein but were not included therein within [***] after receipt thereof. Following receipt of such notice, Licensee will promptly deliver to Relay the additional information requested by Relay to complete the Opt-In Data Package. For clarity, delivery of such incomplete Opt-In Data Package will not trigger the [***] period after which the Opt-In Deadline would occur pursuant to Section 4.1.2, but such [***] period after which the Opt-In Deadline would occur pursuant to Section 4.1.2 will thereafter be triggered on the date of Relay's receipt of the additional information requested by Relay to complete such Opt-In Data Package (such date of receipt in no event to exceed the [***] period described above).

4.1.5 Following delivery of the complete Opt-In Data Package, and prior to the Opt-In Deadline, Licensee will make its representatives reasonably available to Relay to discuss future Development of the Lead Products.

4.1.6 Relay will have the right, in its sole discretion, to exercise the Opt-In Right by delivering to Licensee by the Opt-In Deadline written notice of exercise (each such notice, the "**Opt-In Exercise Notice**"). If Relay provides an Opt-In Exercise Notice prior to the Opt-In Deadline, then (a) Relay will have exercised the Opt-In Right, and (b) the date of receipt of such Opt-In Exercise Notice will be the "**Opt-In Effective Date**". If Relay fails to provide an Opt-In Exercise Notice prior to the Opt-In Deadline, the Opt-In Right will expire and be of no further force or effect.

4.1.7 As of the Opt-In Effective Date, (a) Section 11.2 will apply with respect to the Shared Products and (b) notwithstanding anything to the contrary in Section 3.4, the proposed, updated Global Development Plan will be binding with respect to Shared Products in the Profit Share Territory until such plan is thereafter updated or amended in accordance with Section 3.4.

If prior to the Opt-In Effective Date, Licensee has paid to Relay any Development/Commercial Milestone, and Relay later exercises its Opt-In Right, then Relay will repay the corresponding Development/Commercial Milestone Payment to Licensee either (i) [***] following the Opt-In Effective Date or (ii) in equal installments due on or prior to the beginning of each of the next four (4) Calendar Quarters.

4.1.8 As of the Opt-In Effective Date and prior to the Opt-Out Date, the Sections of this Agreement that apply to the Shared Products during the Opt-In Term shall apply.

4.2 Opt-Out Right.

4.2.1 At any time prior to the third (3rd) anniversary of the First Commercial Sale of the first Shared Product in the Profit Share Territory, Relay has the right, at its sole discretion, to opt-out of further participation in co-funding Development and Commercialization activities for the Shared Products with respect to the Profit Share Territory by providing Licensee with written notice thereof, which election will become effective on the first day of the first Calendar Quarter that begins on or after the [***] anniversary of the date of such election (the "**Opt-Out Date**") for the remainder of the Term (the "**Opt-Out Right**"). As of the Opt-Out Date and continuing for the remainder of the Term, (a) all Shared Products will automatically become Lead Royalty Products, (b) Licensee will be solely responsible for all Development Costs, Launch Costs and Commercialization costs for all Licensed Products in the Territory incurred thereafter, (c) Licensee will continue to comply with its diligence obligations in Section 3.6 and (d) Licensee will provide the reports in accordance with Sections 3.9.

4.2.2 In the event that Relay materially breaches its obligations to share Development Costs and Launch Costs with respect to the Shared Products in accordance with Section 11.3.1, and fails to cure such breach within [***] after written notice thereof is given by Licensee to Relay specifying the nature of the alleged breach, or Relay materially breaches its obligations under Article 9 (Exclusivity), 12.1 (Licenses), or 12.6 (Third Party Licenses), or its obligations under the SAE Management Plan, Quality Agreement, or the Pharmacovigilance Agreement, and fails to cure such breach within the applicable Cure Period set forth in Section 16.3 or such other agreement after written notice thereof is given by Licensee to Relay specifying the nature of the alleged breach, in lieu of exercising its termination right for such breach pursuant to Section 16.3. Licensee will have the right to force the exercise by Relay of its Opt-Out Right upon written notice to Relay. In such case, (a) the consequences set forth in Section 4.2.1 will apply and (b) the date of such final written notice will be deemed to be the "Opt-Out Date." Notwithstanding any such forced exercise of Relay's Opt-Out Right, Relay shall remain responsible for its share of all Development Costs and Launch Costs for Shared Products incurred during the Opt-In Term, and shall not be entitled to any reimbursement for any such Development Costs or Launch Costs. Licensee may offset any amounts due from Relay pursuant to Section 11.3.2 and not paid as of the Opt-Out Date against any subsequent payments due from Licensee to Relay hereunder.

ARTICLE 5.
COMMERCIALIZATION.

5.1 General. Subject to the terms and conditions set forth in this Agreement, Licensee will conduct Commercialization activities for the Licensed Products in the Field in the Territory as further set forth in this Article 5. Licensee shall have the sole right and responsibility for all Commercialization activities relating to the Licensed Products in the Field in the Territory, subject to Relay's Coordinated Promotion Right, including its retained rights in Section 12.1.1 and its rights in Section 16.9.

5.2 Commercialization Costs with Respect to Licensed Products.

5.2.1 Profit Share Territory. In the Profit Share Territory:

(a) If Relay exercises its Opt-In Right, then during the Opt-In Term the Parties will share Net Profits and Net Losses in accordance with the Sharing Percentages pursuant to Section 11.3.1.

(b) If Relay exercises its Opt-Out Right, then Licensee will be responsible for all costs and expenses incurred during the period from the Opt-Out Date for the remainder of the Term.

5.2.2 Royalty Territory. As between the Parties, Licensee will be responsible for [***] costs and expenses incurred for [***] Commercialization activities for the Licensed Products in the Royalty Territory.

5.3 Sales and Distribution. Notwithstanding anything to the contrary contained in this Agreement, Licensee and its Affiliates and Sublicensees will, as between the Parties, have the sole right to book sales, warehouse and distribute Licensed Products in the Field in the Territory, subject to Relay's rights in Section 16.9.

5.4 Recalls, Market Withdrawals or Corrective Actions. In the event that any Regulatory Authority issues or requests a recall or takes a similar action in connection with a Licensed Product in the Field in the Territory, Licensee will, as between the Parties, have the sole right to decide whether to conduct a recall, market withdrawal, or corrective action and the manner in which any such recall, market withdrawal, or corrective action will be conducted. Without limiting any indemnification obligation Relay may have under this Agreement, (a) if such recall, market withdrawal or corrective action occurs during the Opt-In Term, all such costs and expenses in the Profit Share Territory will be treated as Allowable Expenses (as applicable), (b) if such recall, market withdrawal or corrective action occurs outside the Opt-In Term, Licensee will bear the costs and expenses of any such recall, market withdrawal or corrective action in the former Profit Share Territory, and (c) Licensee will bear the costs and expenses of any such recall, market withdrawal or corrective action in the Royalty Territory.

5.5 Pricing; Combination Products.

5.5.1 Pricing. Licensee shall have the sole right and responsibility to set the price of Licensed Products, including in Combination Use. [***]. Relay acknowledges that pricing

takes into consideration multiple factors as mentioned above that in the totality may result in pricing the Licensed Candidate or Licensed Product higher or lower than other such pharmaceutical products Commercialized by or on behalf of a Third Party.

5.5.2 Combination Products.

(a) "**Combination Product**" [***].

(b) If Licensee or its Affiliates or Sublicensees sell a Licensed Product in a Combination Product, then the Sales for such Licensed Product shall be calculated by [***].

(c) In the event that such other active ingredient(s) are not sold separately (but such Licensed Product is), the Sales for such Licensed Product shall be calculated by [***].

(d) In the event that such Licensed Product is not sold separately (but such other active ingredient(s) is), the Sales for such Licensed Product shall be calculated by [***].

(e) In the event that Licensee or its Affiliates intend to sell a Combination Product, and do not intend to sell either the Licensed Product or the other active ingredient(s) included in the Combination Product separately, then [***]. In such event, or otherwise in the event that neither the Licensed Product nor the other active ingredient(s) include in a Combination Product are sold separately, the Parties will engage in good faith negotiations for up to [***] to determine the Relative Commercial Value, such negotiations to take into consideration: [***]. If during such time Licensee and Relay cannot agree on the Relative Commercial Value, the Dispute will be referred to the Executive Officers in accordance with Section 18.9.2.

5.6 Coordinated Promotion Right in Connection with Relay Pipeline Combinations.

5.6.1 During the Term, Relay will have the right to co-promote the Relay Pipeline Combination Eligible Licensed Products solely for Combination Use in Relay Pipeline Combinations, throughout the Territory in coordination with Licensee and in compliance with this Agreement and the applicable Coordinated Promotion Agreement (the "**Coordinated Promotion Right**"). At least [***] prior to the date of the anticipated submission of the first NDA for a Relay Pipeline Product that will be marketed as a Relay Pipeline Combination anywhere in the Territory (or such other time as may be mutually agreed by the Parties), the JDT will form a JPT pursuant to Section 10.3. Through the JPT, Licensee will have the right to review and provide comments on Relay's Commercialization activities for such Relay Pipeline Combination (including choice of any contract sales organization, if any are proposed to be used by Relay), which comments Relay will consider in good faith, and if necessary or desirable by Relay, will modify Relay's Commercialization activities in a manner to avoid negative impact on Licensee's Commercialization activities for the relevant Licensed Product. Relay shall not co-package or co-formulate the Relay Pipeline Compound in a Relay Pipeline Combination with the Licensed Candidate without Licensee's prior approval, such approval to be in Licensee's discretion.

5.6.2 At least [***] prior to the date of the anticipated submission of the first NDA for a Relay Pipeline Combination, the Parties will negotiate in good faith and enter into a

written agreement that sets forth the terms of the Parties' activities with respect to the promotion of the Relay Pipeline Combination throughout the Territory, such terms to be consistent with the high-level terms and principles set forth in this Section 5.6 (each such agreement, a "**Coordinated Promotion Agreement**"). The Parties will coordinate the promotion of the Relay Pipeline Combinations in the Territory pursuant to the terms and conditions of this Agreement and the Coordinated Promotion Agreement, [***], subject to Section 16.9. Subject to Section 8.1.4, Relay will be entitled to employ a contract sales organization to perform any of its obligations under a Coordinated Promotion Agreement. Costs and expenses incurred by or on behalf of a Party under any Coordinated Promotion Agreement will be borne as set forth in the Coordinated Promotion Agreement. In the event that the Parties cannot reach resolution on a definitive Coordinated Promotion Agreement within [***] prior to the date of the anticipated submission of the first NDA for a Relay Pipeline Combination, then such Dispute in accordance with Section 16.10 *mutatis mutandis*.

ARTICLE 6.
REGULATORY RESPONSIBILITIES

.

6.1 Regulatory Lead Responsibilities. Subject to Section 5.4, the Regulatory Lead will be solely responsible for all regulatory matters in the Field in the applicable Territory relating to the Licensed Candidates, Licensed Products, [***] Combinations, and Relay Pipeline Combinations for which such Party is the Regulatory Lead. The Regulatory Lead will own all INDs, NDAs, Regulatory Approvals, Regulatory Materials, and related regulatory documents in the Field in the Territory with respect to such Licensed Candidates, Licensed Products, [***] Pipeline Compounds, [***] Combinations, Relay Pipeline Products and Relay Pipeline Combinations including any drug master files maintained by such Regulatory Lead solely with respect thereto in the Territory. Notwithstanding anything herein to the contrary, the Regulatory Lead responsibilities with respect to Relay and Relay Pipeline Combinations apply only to the Relay Pipeline Products contained in a Relay Pipeline Combinations and the Relay Pipeline Combination taken as a whole but not with respect to the Relay Pipeline Combination Eligible Licensed Product contained therein on its own.

6.2 Drug Master Files. If Licensee does not have access to or rights to cross reference any drug master files maintained by any Third Party (including any contract manufacturer) pursuant to Section 6.4 reasonably sufficient to permit Licensee to exercise its rights and comply with its regulatory obligations, in each case, in connection with the Development, Manufacture and Commercialization of Licensed Candidates or Licensed Products in the Field in the Territory under this Agreement, then, (a) with respect to any agreement between Relay and any such Third Party that exists as of the Effective Date, Relay will use Commercially Reasonable Efforts to secure for Licensee such reasonably sufficient access to or rights to cross reference any such drug master files maintained by such Third Party, and (b) with respect to any agreement between Relay and any such Third Party that is entered into on or after the Effective Date, Relay shall use Commercially Reasonable Efforts to secure for Licensee such reasonably sufficient access to or rights to cross reference any such drug master files maintained by such Third Party solely with respect to Licensed Candidates or Licensed Products.

6.3 Relay Phase Ia Trial. This Section 6.3 will apply to the conduct of the Relay Phase Ia Trial.

6.3.1 Prior to Relay IND Transfer Date. While Relay is acting as Sponsor of the Relay Phase Ia Trial, the following shall apply:

(a) Relay will immediately provide Licensee (through the JDT after it is formed) each Material Communication from or with Regulatory Authorities with respect to the Relay Phase Ia Trial. Relay will further provide descriptions of and copies of such Material Communications as part of the updates to the JDT regarding Development activities described in Section 3.9 after the JDT is formed. With respect to any Material Communication with a Regulatory Authority, Relay will allow Licensee a reasonable opportunity to review and comment on such proposed Material Communication or response thereto in advance of submission to the Regulatory Authority, and will reasonably consider all comments timely provided by Licensee in connection therewith.

(b) Relay will provide Licensee with reasonable advance notice of all meetings with the Governmental Authorities pertaining to the Relay Phase Ia Trial, or with as much advance notice as practicable under the circumstances. If permitted by the relevant Governmental Authority, Licensee may have up to [***] representatives attend all such meetings; provided that Licensee will not select representatives to attend such meetings whose availability would unreasonably delay any such meeting. Relay will also provide Licensee, in advance of such meetings, with any briefing documents or other materials associated with these meetings, will participate with Licensee in a pre-meeting to prepare for such meeting, and will reasonably consider all comments timely provided by Licensee in connection therewith. If a Governmental Authority contacts Licensee with respect to the Relay Phase Ia Trial, Licensee shall immediately inform Relay of the same and the Parties will coordinate on a response.

(c) Relay will provide Licensee with a copy of all proposed material regulatory submissions with respect to the Relay Phase Ia Trial for the other Party's review and comment sufficiently in advance of Relay's filing or submission thereof, and Relay will reasonably consider all comments timely provided by Licensee in connection therewith (and Licensee's approval will be required to the extent Licensee has final say on such submission or the matter to which such submission relates as provided in 10.7.3(b)).

6.3.2 After Relay IND Transfer Date. While Licensee is acting as Sponsor of the Relay Phase Ia Trial, the following shall apply:

(a) Licensee will immediately provide Relay any communication received by Licensee from Governmental Authorities with respect to the Relay Phase Ia Trial. Relay will reasonably assist in responding to queries of Governmental Authorities as requested by Licensee, including providing to Licensee immediately (within [***]) after request any data and information in Relay's Control that was not previously transferred to Licensee and that Licensee reasonably determines is necessary or desirable to respond to any such query.

(b) Relay will reasonably assist in preparing regulatory submissions and responding to queries from Governmental Authorities with respect to the Relay Phase Ia Trial as requested by Licensee, including the portions of any regulatory filing documentation relating to the Manufacture and supply of Phase Ia Product for the Relay Phase Ia Trial or other activities and responsibilities conducted by Relay in connection with the Relay Phase Ia Trial.

(c) If reasonably requested by Licensee, Relay will make appropriate Relay representatives available to participate in meetings with Governmental Authorities pertaining to the Relay Phase Ia Trial or in pre-meetings with Licensee to prepare for such meetings. Licensee will make such request reasonably in advance of the meeting, or with as much advance notice as practicable under the circumstances.

(d) Relay shall reasonably cooperate with Licensee and provide any other assistance reasonably requested by Licensee with respect to any such regulatory activities conducted by Licensee with respect to the Relay Phase Ia Trial.

6.4 Ongoing Support for Development. Relay will also use Commercially Reasonable Efforts to support Licensee as reasonably requested in support of preparation, submission and prosecution of regulatory submissions to, and responding to queries from, Governmental Authorities for Licensee Combinations, including preparation (data cleaning, tables and listings) of data to support dose decisions, Phase Ib Clinical Trial study design and preparation and summaries of data sets to support global filings and assistance with requests from Governmental Authorities related to new and existing data, dose justification and safety, preclinical experiments and assays conducted by Relay.

6.5 Right of Reference. Each Party hereby grants to the other Party, and at the request of the other Party will grant to the other Party's Affiliates and Sublicensees, a **"Right of Reference,"** as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous Applicable Law recognized outside of the United States), to, and a right to copy, access, and otherwise use, all information and data (including all CMC information as well as data made, collected, or otherwise generated in the conduct of any Clinical Trials, or early access/named patient programs for any Licensed Candidates or Licensed Products included in or used in support of any regulatory filing, Regulatory Approval, drug master file) or other regulatory documentation (including orphan drug applications and designations) Controlled by such Party or its Affiliates or Sublicensees that relates to any Licensed Candidates or Licensed Products solely for the purpose of (a) in the case of Licensee, obtaining or maintaining any IND or Regulatory Approval of any Licensed Candidates or Licensed Products (including any Licensee Combination) or (b) in the case of Relay, obtaining or maintaining any IND or Regulatory Approval for any Relay Pipeline Combination or Relay Pipeline Product. Licensee will provide Relay with copies of Regulatory Materials related to any Relay Pipeline Combination Eligible Licensed Products that are reasonably requested by Relay for use by or on behalf of Relay, its Affiliates or Relay Sublicensees in connection with Developing, Manufacturing or Commercializing any Relay Pipeline Combination as permitted hereunder. In addition, upon the reasonable request of the other Party (on behalf of itself or a Sublicensee), each Party will provide a signed statement to this effect, if requested by the other Party, in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor or analogous Applicable Law outside of the United States) that the other Party may rely on, and the Regulatory Authority may access, in support of the other Party's application for Regulatory Approval in its Territory, any underlying raw data or information submitted by such Party to the Regulatory Authority with respect to any regulatory submission, Regulatory Approval, drug master file, or other regulatory documentation (including orphan drug applications and designations) Controlled by such Party or its Affiliates or Sublicensees that relates to any Licensed Candidates or Licensed Products or Licensee Combinations or Relay Pipeline Combinations, as applicable. In addition, upon reasonable request of either Party (on behalf of itself or a

Sublicensee), the other Party will obtain and provide to the requesting Party certificates or other formal or official attestations concerning the regulatory status of any Licensed Candidates or Licensed Products or Licensee Combinations or Relay Pipeline Combinations, as applicable, in the Territory (e.g., Certificates of Free Sale, Certificates for Export, Certificates to Foreign Governments), in each case, as is reasonably necessary for the requesting Party to exercise its rights under this Agreement. Other than for safety concerns, notwithstanding anything in this Agreement to the contrary, neither Party will withdraw or inactivate any regulatory filing that the other Party references or otherwise uses pursuant to this Section 6.5 unless otherwise mutually agreed by the Parties.

6.6 Pharmacovigilance. Upon the request of a Party, the Parties will negotiate in good faith and enter into a separate pharmacovigilance agreement at least [***] prior to filing the IND for the first Relay Pipeline Compound in a Relay Pipeline Combination (the "**Pharmacovigilance Agreement**"), which will govern the exchange of safety data information, adverse events reporting and Licensed Product complaints to ensure timely communication to Regulatory Authorities and compliance with Applicable Law.

6.7 Costs of Regulatory Affairs.

6.7.1 During the Opt-In Term, [***].

6.7.2 Outside the Opt-In Term, [***].

6.7.3 During the Opt-In Term, [***].

6.7.4 Relay will be responsible for [***].

6.8 NDA [***]. It is understood and acknowledged that, for each Relay Pipeline Combination, Relay [***]. If, after using Commercially Reasonable Efforts [***], Relay anticipates, based upon reasonable inquiry with the applicable Regulatory Authority, that [***] may be required, then at least [***] prior to filing [***] for such Relay Pipeline Combination, Relay will provide written notice to Licensee of such potential requirement, and the Parties will cooperate to review and discuss potential alternatives [***], including [***].

ARTICLE 7.
MANUFACTURING.

7.1 Generally. Except as otherwise expressly provided in Section 7.2, Licensee shall have the sole right and responsibility for the Manufacturing and supplying of Licensed Candidates and Licensed Products for clinical supply or commercial supply, except for the supplying of the Phase Ia Product as described below.

7.2 Responsibilities for Supply.

7.2.1 Relay will be responsible (itself or via a CMO), at its expense, for supplying the Phase Ia Product required for the Relay Phase Ia Trial conducted under the Relay Phase Ia Plan as such plan exists as of the Execution Date or as may be modified in accordance with Section 3.3.2 or 3.4.2, as applicable, except that if Relay runs out of such Phase Ia Product in its inventory

and is unable to supply thereafter, Licensee will supply, at its expense, by itself or via a CMO, the Phase Ia Product for the remainder of the Phase Ia Clinical Trial.

7.2.2 During the Term, Licensee will be responsible (itself or via a CMO), at its expense, for Manufacturing and supplying any Licensed Candidate or Licensed Product required for the Development or Commercialization of such Licensed Candidate or Licensed Product, except that for clinical supply of Shared Products under the Global Development Plan, Relay's obligations with respect to reimbursement of its share of Development Costs for Shared Products pursuant to Section 11.2 shall apply.

7.2.3 Subject to Sections 7.2.4 and 16.9, Licensee will have the sole right and responsibility (itself or via a CMO), subject to Relay's back-up rights in accordance with the Supply Agreement, for Manufacturing and supplying Finished Products that Licensee is then-currently Manufacturing for the Development of Licensee Combinations for clinical supply for the Development activities for Relay Pipeline Combinations. If Licensee supplies such Finished Products under this Section 7.2.3, then Licensee will provide such clinical supply at Licensee's expense.

7.2.4 Promptly after the Effective Date, and in any event within [***] following the Effective Date, the Parties will negotiate in good faith, and execute, a definitive supply agreement pursuant to which Licensee will supply such clinical supply of Finished Product to Relay ("**Supply Agreement**"). [***]. Notwithstanding anything in the foregoing, whether or not the Supply Agreement has been executed, Relay shall provide an initial forecast to Licensee at least [***] prior to anticipated commencement of its Clinical Trial for which such supply is requested for Licensee's planning purposes.

ARTICLE 8.
COMPLIANCE PROVISIONS

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8.1 General.

8.1.1 Compliance with Laws. Each Party shall use Commercially Reasonable Efforts to conduct, and to ensure its Affiliates and Third Party Subcontractors conduct, all activities hereunder in compliance with all Applicable Law.

8.1.2 Debarment. Each Party hereby certifies that it is not, and that to its Knowledge it has not employed or otherwise used, and will not knowingly employ or otherwise use, the services of any Person (including any employee, officer, director, Affiliate or Third Party contractor) that is (a) debarred under United States law (including 21 USC §335a), disqualified under 21 C.F.R. Parts 56, 58 or 312, or any foreign equivalent thereof or (b) the subject of an HHS or FDA debarment or disqualification investigation or proceeding (or similar proceeding by any Regulatory Authority outside the United States), in each case, in the performance of Development or Commercialization activities under this Agreement. Each Party will notify the other Party in writing promptly if any such debarment or disqualification comes to its attention, and will, with respect to any Person or entity so debarred promptly remove such Person or entity from performing any such activities.

8.1.3 Violations. Each Party hereby certifies that it is not in Violation, and that to its Knowledge it has not employed or used, and will not employ or otherwise use, the services of any Person (including any employee, officer, director, Affiliate or Third Party contractor) who is in Violation in the performance of Development or Commercialization activities under this Agreement. Each Party will notify the other Party in writing promptly if any such Violation comes to its attention.

8.1.4 Subcontractors. Each Party will be entitled to utilize the services of Third Party Subcontractors to perform activities under this Agreement, provided that (a) the Party engaging a Third Party Subcontractor (the "**Subcontracting Party**") will require that such Third Party Subcontractor satisfies its obligations in a manner consistent with the terms of this Agreement and (b) the Subcontracting Party will remain at all times fully liable for such Party's responsibilities and for any actions or omissions by such Third Party Subcontractor that may be a breach of this Agreement, subject to the last sentence of Section 16.3. Each Third Party Subcontractor Agreement entered into by a Party after the Effective Date will (i) include confidentiality and non-use provisions that are substantially similar to those set forth in Article 13 (but of duration customary in confidentiality agreements entered into for a similar purpose); and (ii) assign ownership of, or grant a fully sublicensable license under and to, any Know-How and Patents that are created, conceived or generated by such Third Party Subcontractor in the performance of such agreement and are necessary or reasonably useful to Research, Develop, Manufacture or Commercialize Licensed Candidates or Licensed Products. For clarity, the foregoing requirement to obtain ownership of, or a fully sublicensable license will not apply to any improvements to the proprietary core or platform technology owned or in-licensed by any such Third Party Subcontractor or its Affiliates unless such improvements are necessary or reasonably useful to Research, Develop, Manufacture or Commercialize those Licensed Candidates or Licensed Products with respect to which a Party or its Affiliate conducted its activities under such Third Party Subcontractor Agreement.

ARTICLE 9.
EXCLUSIVITY.

9.1 General.

9.1.1 Commencing on the Effective Date and continuing until the third (3rd) anniversary of the First Commercial Sale of the first Licensed Product (whether a Shared Product or a Royalty Product) in the Territory (or Profit Share Territory, as applicable), except for the performance of activities in accordance with this Agreement and the Supply Agreement, neither Relay nor its Affiliates will directly or indirectly, Research, Develop, Manufacture or Commercialize any molecule Directed to the Collaboration Target; provided that Relay and its Affiliates may directly or indirectly Develop the Relay Pipeline Combination Eligible Licensed Products and co-promote, in coordination with Licensee and in accordance with this Agreement and any applicable Coordinated Promotion Agreement, the Relay Pipeline Combination Eligible Licensed Products, in each case solely for Combination Use in Relay Pipeline Combinations.

9.1.2 Commencing on the Effective Date and continuing until the third (3rd) anniversary thereof, Genentech will cause gRED not to conduct a Pivotal Trial for a molecule

Directed to the Collaboration Target other than a Licensed Candidate or Licensed Product pursuant to this Agreement [***].

9.1.3 Notwithstanding anything herein to the contrary, Relay and its Affiliates will have the right to [***], (ii) as between Licensee and Relay, Relay will remain at all times fully liable for any actions or omissions by such Third Party that may be a breach of this Agreement, subject to the last sentence of Section 16.3, and (iii) Relay or its Affiliate obtain exclusive ownership in the Field of, or a fully sublicensable exclusive license in the Field (or, solely with respect to an academic institution, university or non-commercial Third Party, an option to obtain or negotiate such license limited to Patents) under and to, any Know-How and Patents specifically related to such Licensed Candidates that are created, conceived or generated by such Third Party in the exercise of such rights under such agreement and (iv) and the right to share data and reports with Licensee and for Licensee to use such data and reports in accordance with the rights granted hereunder; provided, further, that in each case of (a) and (b) above, [***]. For the avoidance of doubt, notwithstanding anything to the contrary in Section 13.6, Relay and its Affiliates may not make any Publication with respect to activities conducted pursuant to this Section 9.1.3 without the prior written approval of Licensee in its sole and absolute discretion.

9.2 Acquired Programs.

9.2.1 Acquired Programs Generally. Notwithstanding Section 9.1, in the event Relay or its Affiliate acquires a Third Party (by merger, sale, consolidation, reorganization, or other Change of Control) so that such Third Party becomes an Affiliate of Relay, or Relay or its Affiliate acquires all or substantially all of the assets of a Third Party (including any subsidiaries or divisions thereof), and as of the date of such acquisition, such Third Party has, or the acquired assets contain a program or product that existed prior to such acquisition that would otherwise violate Section 9.1 (an "**Acquired Program**"), then Relay will not be deemed to be in violation of Section 9.1 provided that Relay either (a) divests its rights to such Acquired Program in accordance with Section 9.2.2, or (b) terminates such Acquired Program in accordance with Section 9.2.3, and, in each case ((a) or (b)), provides prompt written notice to Licensee within [***] after the closing of the acquisition of such Acquired Program and whether the acquiring Party is electing (i) or (ii).

9.2.2 Divestment of Acquired Program. If Relay elects to divest its rights to an Acquired Program, then Relay (and its Affiliates, if applicable) will divest such Acquired Program within [***] following the closing of the applicable acquisition under Section 9.2.1 (provided that such period may be extended for up to an additional [***] after closing if Relay and its Affiliates are using diligent efforts to divest such Acquired Program); provided that for so long as Relay or its Affiliates retain such Acquired Program the Acquired Program is segregated in accordance with Section 9.2.4.

9.2.3 Termination of Acquired Program. If Relay elects to terminate an Acquired Program, then Relay (and its Affiliates, if applicable) will cease any activities under such Acquired Program as soon as reasonably practicable and in any event within [***] of the closing of the applicable acquisition under Section 9.2.1, giving due consideration to ethical concerns and requirements under Applicable Law; provided that for so long as Relay or its Affiliates retain such Acquired Program, the Acquired Program is segregated in accordance with Section 9.2.4.

9.2.4 Segregation of Programs. During any period prior to divestment or termination of an Acquired Program pursuant to Section 9.2.2 or 9.2.3, as applicable, Relay may conduct such Acquired Program to the extent permitted by this Section 9.2.4; provided that, (a) none of the Relay Patents and Relay Know-How or Licensee IP will be used in the Acquired Program, and (b) the activities required under this Agreement will be conducted separately from any research, development, manufacturing, and commercialization activities (as applicable) directed to such Acquired Program, including establishing reasonable protections and safeguards, [***].

9.3 Acquirer Programs. Notwithstanding Section 9.1, in the event Relay is acquired by a Third Party (by merger, sale, consolidation, reorganization or other Change of Control) so that such Third Party becomes an Affiliate of Relay or is merged into Relay or Relay is merged into such Third Party, and, as of the date of such acquisition or later, such Third Party has a program or product that would otherwise violate Section 9.1 (an "**Acquirer Program**"), then such Party will not be deemed to be in violation of Section 9.1 and may continue such Acquirer Program subject to Section 18.3. In addition to the requirements of Section 18.3: [***].

ARTICLE 10.
GOVERNANCE; REPORTING

10.1 Joint Teams. The Parties will establish a joint development team ("**JDT**") to oversee the Development of Licensed Candidates and Licensed Products in the Field in the Territory and, a joint promotion team ("**JPT**") to oversee the activities of the Parties with respect to the promotion of the Relay Pipeline Combination Eligible Licensed Product included in a Relay Pipeline Combination. Each Joint Team has the authority (a) for matters specifically delegated to it or expressly specified in this Agreement, (b) to resolve disputes within the jurisdiction of such Joint Team, and (c) with respect to any other matter agreed to by the Parties in writing. For clarity, neither Joint Team will have any power to amend, modify, or waive compliance with this Agreement. The Joint Teams have no other authority under this Agreement.

10.2 Joint Development Team

.

10.2.1 Establishment. Within [***] after the Effective Date, the Parties will establish a JDT as more fully described in this Section 10.2. The JDT will oversee the Development of Licensed Candidates and Licensed Products in the Field in the Territory, to the extent expressly and as more specifically provided in Section 10.2.2. Each Party agrees to keep the JDT informed of its progress and activities under this Agreement.

10.2.2 Responsibilities. The JDT will have the following responsibilities with respect to the Development of Licensed Candidates and Licensed Products under this Agreement: [***].

10.3 Joint Promotion Team

10.3.1 Establishment. In accordance with Sections 5.6.1, the Parties will establish a JPT with respect to Relay Pipeline Combinations at least [***] prior to the date of the anticipated submission of the first NDA for a Relay Pipeline Combination. The JPT will coordinate the

activities of the Parties with respect to the promotion of the Relay Pipeline Combination Eligible Licensed Products that are contained in Relay Pipeline Combinations and will serve as a forum for the coordination of such promotion activities to the extent expressly and as more specifically provided in Section 10.3.2. Each Party agrees to keep the JPT informed of its progress and activities with respect to coordinated promotion of such Relay Pipeline Combinations.

10.3.2 Specific Responsibilities. The JPT will have the following responsibilities with respect to the coordinated promotion of the Relay Pipeline Combinations under this Agreement: [***].

10.4 Membership. Each Joint Team will be comprised of [***] representatives (or such other number of representatives as the Parties may mutually agree; provided that such Joint Team will consist at all times of an equal number of representatives of each Party, unless otherwise agreed by the Parties in writing) from each of Licensee and Relay. Unless otherwise agreed by Licensee, Relay's representatives will include its [***]. Each representative of a Party will have sufficient seniority and expertise to participate on the applicable Joint Team as determined in such Party's reasonable judgment. Licensee will designate a chairperson for each Joint Team, which chairperson will be responsible for developing, in consultation with the representatives of Relay, and circulating the agenda for the applicable Joint Team meeting reasonably in advance thereof. No chairperson will have additional powers or rights beyond those held by the other representative for the applicable Joint Team. Each Party may replace any or all of its representatives on a Joint Team at any time upon written notice to the other Party in accordance with Section 18.10.

10.5 Meetings.

10.5.1 The first scheduled meeting of the JDT will be held no later than [***] after establishment of the JDT unless otherwise agreed by the Parties. After the first scheduled meeting of the JDT and until delivery of the TLF to Licensee pursuant to Section 4.1.2, the JDT will meet at least [***], or more or less frequently as the Parties mutually deem appropriate, on such dates and at such places and times as provided herein or as the Parties otherwise agree. After delivery of the TLF to Licensee pursuant to Section 4.1.2 and until the JDT is disbanded in accordance with Section 10.8, the JDT will meet at least once [***], or more or less frequently as the Parties mutually deem appropriate, on such dates and at such places and times as provided herein or as the Parties otherwise agree.

10.5.2 The first scheduled meeting of the JPT will be held no later than [***] after establishment thereof unless otherwise agreed by the Parties. After the first scheduled meeting of the JPT and until the JPT is disbanded in accordance with Section 10.8, the JPT will meet at least once [***], or more or less frequently as the Parties mutually deem appropriate, on such dates and at such places and times as provided herein or as the Parties otherwise agree.

10.5.3 The members of each Joint Team may meet by means of telecommunications, video conferences, electronic mail or correspondence, as deemed necessary or appropriate. Notwithstanding the foregoing, at least [***] meeting of each Joint Team per Calendar Year will be in-person, unless the Parties agree otherwise. The location of the in-person meetings will be mutually agreed by the Parties.

10.5.4 Each Party may invite a reasonable number of non-member representatives of such Party and any Third Party to attend meetings of any Joint Team as observers; provided, that any such representative or Third Party is bound by obligations of confidentiality, non-disclosure and non-use consistent with those set forth in Article 13 prior to attending such meeting.

10.5.5 [***]. Meetings of each Joint Team are only effective if at least [***] representative from each Party is present or participating in such meeting.

10.6 Procedural Rules. Each Joint Team will have the right to adopt such standing rules as will be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the Joint Team will exist whenever there is present at a meeting at least [***] representative appointed by each Party. Each Joint Team will take action or make decisions at a meeting at which a quorum exists, or by a written resolution signed by at least [***] appointed by each Party.

10.7 Decision Making. Subject to the remainder of this Section 10.7, each Joint Team will make decisions by unanimous agreement. The representatives from each Party on any Joint Team will have, collectively, [***] vote on behalf of that Party. Except as otherwise expressly set forth in this Agreement, the phrase "determine," "designate," "approve" or "determine whether to approve" by a Joint Team and similar phrases used in this Agreement will mean approval in accordance with this Section 10.7, including the tie breaking provisions herein.

10.7.1 Decisions of the JPT. The JPT will use good faith efforts to promptly resolve any matter for which it has authority. Notwithstanding the foregoing, for any matter over which Party has final decision-making authority pursuant to Section 10.7.3, such Party may make the decision on such matter at any time, without waiting for the JPT to reach agreement on such matter.

10.7.2 Decisions of the JDT. The JDT will use good faith efforts to promptly resolve any matter for which it has authority. Notwithstanding the foregoing, for any matter over which Party has final decision-making authority pursuant to Section 10.7.3, such Party may make the decision on such matter at any time, without waiting for the JDT to reach agreement on such matter.

10.7.3 Final Decision Making Authority. If the Joint Team is unable to reach unanimous agreement on any matter for which the Joint Team is responsible, then,

(a) Relay Decisions. [***]

(b) Licensee Decisions. [***]

(c) [***].

(d) Notwithstanding clause (ii) of Section 10.7.3(b), in the event Licensee requests to amend or change the Relay Phase Ia Plan to add an Optional Additional Phase Ia Study or a Required Additional Phase Ia Study, such request will be subject to Relay's rights in Section 3.3.2 or Section 3.4.2, as applicable.

In any case, Licensee may move forward without delay on any activities for which it believes in good faith that it has final decision making authority regardless of any dispute, which would be escalated independently of the applicable Joint Team.

10.8 Minutes. The Parties will alternate responsibility (with Licensee having such responsibility first) for preparing and circulating minutes of each meeting of each Joint Team, setting forth, *inter alia*, an overview of the discussions at the meeting. Such minutes will be effective only after such minutes have been approved by both Parties in writing or by e-mail, with any differences in the Parties' recollections noted in such finalized minutes. Definitive minutes of all Joint Team meetings will be finalized no later than [***] after the meeting to which the minutes pertain.

10.9 Disbandment. The JDT will disband upon the earlier of [***]. The JPT will disband upon the earlier of [***]. Following the disbandment of all Joint Teams, all notices required to be delivered by a Party to the Joint Teams will thereafter be provided to the other Party in accordance with Section 18.12.

10.10 Sub-Committees and Working Groups. Each Joint Team may establish sub-committees or working groups to interact on a more frequent basis on specific projects and tasks assigned to them by such Joint Team; provided, that the authority of such sub-committees or working groups will not expand beyond the authority of the applicable Joint Team. Any such sub-committees or working groups will have no decision-making authority but will make recommendations to the applicable Joint Team for its review and approval.

10.11 Limitations on Authority. Each Party will retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion will be delegated to or vested in a Joint Team unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. No Joint Team will have the power to amend, modify, or waive compliance with this Agreement, which may only be amended or modified as provided in Section 18.15 or compliance with which may only be waived as provided in Section 18.15.

10.12 Financial Liaisons. [***].

10.13 Alliance Managers

. Promptly after the Effective Date, each Party will appoint an individual to act as alliance manager for such Party who possesses a general understanding of this Agreement and the conduct of activities hereunder and who will oversee contact between the Parties for all matters between meetings of each Joint Team and will have such other responsibilities as the Parties may agree in writing after the Effective Date (each, an "**Alliance Manager**"). The Alliance Managers may attend all meetings of the JDT as non-voting participants and will be responsible for assisting the JDT in performing its informational and review responsibilities. The name and contact information for each Party's Alliance Manager, as well as any replacement(s) chosen by such Party, in its sole discretion, from time to time, will be promptly provided to the other Party in accordance with Section 18.10. Each Party may replace its Alliance Manager at any time by notice in writing to the other Party.

ARTICLE 11.
FINANCIAL TERMS

11.1 Upfront Payment and IND Transfer and Phase Ia Completion Payments.

11.1.1 Upfront Payment. As partial consideration for the licenses and other rights granted by Relay to Licensee under this Agreement, Licensee will pay Relay, in accordance with Section 11.1.4, a non-refundable, non-creditable initial payment of Seventy Five Million Dollars ($75,000,000) upon completion of all activities under the Technology Transfer Plan that are scheduled to be completed as of the Effective Date, including providing Licensee with complete access (including the ability to download) to all information and data in the data room to which Licensee was provided "read only" access as part of its due diligence activities conducted prior to the Execution Date (the "**Immediate Tech Transfer Activities**").

11.1.2 IND Transfer Payment. As partial consideration for the licenses and other rights granted to Licensee hereunder, Licensee will pay to Relay, in accordance with Section 11.1.4, [***] upon completion of the Relay IND Transfer, including completion of all activities that are conditions to the Relay IND Transfer as described in Section 3.2.3(b), and completion of all activities under the Technology Transfer Plan that are scheduled to be completed within [***] after the Effective Date (the "**IND Transfer Milestone**").

11.1.3 Relay Phase Ia Trial Payment. As partial consideration for the licenses and other rights granted to Licensee hereunder, Licensee will pay to Relay, in accordance with Section 11.1.4, the non-refundable, [***] (the "**Relay Phase Ia Trial Milestone**"). Notwithstanding the foregoing, if the Relay Phase Ia Trial is transferred to Licensee pursuant to Section 3.4.7, then Licensee will pay Relay the Relay Phase Ia Trial Milestone upon the later of (i) Licensee's confirmation of complete transfer of the Relay Phase Ia Trial as directed pursuant to Section 3.4.7 and (ii) Licensee's receipt of the complete TLF, whichever occurs later; provided that if Licensee requested such transfer of the Relay Phase Ia Trial based upon breach by Relay as set forth in such Section 3.4.7, then no Relay Phase Ia Trial Milestone will be due or paid.

11.1.4 Payment of Upfront, IND Transfer and Relay Phase Ia Trial Payments. Licensee will provide Relay with written notice of completion of the Immediate Tech Transfer Activities or achievement of the IND Transfer Milestone or the Relay Phase Ia Trial Milestone, as applicable, promptly after Licensee's confirmation of the achievement thereof and confirmation that Relay is in material compliance with all of its obligations with respect to the Technology Transfer and relevant obligations under Sections 3.2, 3.3, 3.4, 3.9.1, 6.3 and 6.4 through such date. Relay shall invoice Licensee upon receipt of such notice from Licensee, and Licensee will make the corresponding payment within [***] after receipt of Relay's invoice from Relay thereafter for the corresponding payment (or [***] in the case of the initial payment pursuant to Section 11.1.1). If Licensee is unable to confirm the foregoing, Licensee will promptly notify Relay in writing and the reasons Licensee is unable to confirm, including identifying any items that, in Licensee's reasonable determination made in good faith, are still needed for achievement of the milestone or compliance with Relay's obligations under Sections 3.2, 3.3, 3.4, 3.9.1, 6.3 and 6.4.

11.2 Relay Phase Ia Trial CRO Costs. Relay Phase Ia Trial CRO Costs will be shared in accordance with Section 3.8.1. Relay will report to Licensee, within [***] after the end of each Calendar Quarter, the Relay Phase Ia Trial CRO Costs incurred by Relay during such Calendar Quarter. Such report will specify in reasonable detail (including supporting documentation, as appropriate) all amounts included in such Relay Phase Ia Trial CRO Costs during such Calendar Quarter. Concurrently with or after delivery of such report, Relay will deliver an invoice to Licensee for Licensee's share of such Relay Phase Ia Trial CRO Costs. Payment by Licensee will be due [***] after receiving such an invoice from Relay pursuant to this Section 11.2.

11.3 Development Costs During the Opt-In Term; Launch Costs. During the Opt-In Term:

11.3.1 Development Costs relating to the GDP; Launch Costs.

(a) Development Costs incurred by Licensee for Shared Products pursuant to the GDP (including for the avoidance of doubt Development Costs incurred prior to the Opt-In Effective Date) and Launch Costs incurred by Licensee for Shared Products will be shared in accordance with the Sharing Percentages. [***]. Any Development for any such Licensee Combination after Regulatory Approval for the [***] Indication in the Profit Share Territory will be made under the GDP, and the GDP will be updated accordingly and Development Costs and Launch Costs will be shared in accordance with the applicable Sharing Percentages.

(b) In addition, Relay will have the right, in its sole discretion, upon written notice to Licensee [***]. If Relay exercises such right, the Second Tier GDP Overrun for such Calendar Year [***] Notwithstanding the foregoing, at its option [***] or any portion thereof against subsequent payments owed by Licensee to Relay under Section 11.5.1, 11.5.2, 11.5.4, 11.5.5, 11.6.1 or 11.6.2 until paid. For the avoidance of doubt, [***].

11.3.2 Costs incurred by Licensee during such Calendar Quarter in accordance with the GDP with respect to Shared Products. Licensee will provide Relay with a written report within [***] after the end of each Calendar Quarter indicating the Development Costs and Launch Costs incurred by Licensee, in each case, in accordance with the GDP in the just-ended Calendar Quarter. Each such report will specify in reasonable [***]. If Relay has not reported and issued an invoice to Licensee for reimbursement of Licensee's share of development costs for a Relay Pipeline Combination during such just-ended Calendar Quarter calculated in accordance with Section 3.8.2, Licensee will thereafter deliver an invoice to Relay for any amounts due to Licensee. If Relay has also reported and issued an invoice to Licensee for reimbursement of Licensee's share of development costs for a Relay Pipeline Combination during such just-ended Calendar Quarter as provided in Section 3.8.2, Licensee will prepare a reconciliation report for such Calendar Quarter and will deliver an invoice to Relay for any amounts due to Licensee after such reconciliation (or request an invoice from Relay for any amounts due to Relay after such reconciliation). If Relay has any questions related to the foregoing reports, Relay may raise such questions with Licensee (through the applicable financial sub-committee or working group under the JDT if one has been formed or otherwise through the JDT) and the Parties will seek to promptly resolve any such questions. Payment by a Party will be due [***] after receiving an invoice from the other Party pursuant to this Section 11.3.2.

11.3.3 FTE Records and Calculations. Licensee will record and account for its FTE effort to the extent that such FTE efforts are included in Development Costs or Launch Costs in accordance with the GDP with respect to Shared Products for the Profit Share Territory. Licensee will allocate and maintain records of FTE effort incurred by it in the same manner as used for other products developed by Licensee.

11.4 Net Profits and Net Losses Share. For so long as there is a sale of a Shared Product in the Profit Share Territory, the terms and conditions of this Section 11.4 will govern each Party's rights and obligations with respect to Net Profits and Net Losses relating to Shared Products in the Profit Share Territory during the Opt-In Term. Subject to this Section 11.4, Net Profits and Net Losses with respect to each Shared Product will be shared equally by the Parties.

11.4.1 Net Profits and Net Losses Reports and Payments. In the event that this Section 11.4 applies:

(a) Licensee will report to Relay within [***] after the end of each Calendar Quarter, a good faith, non-binding estimate of Net Profits and Net Losses that will be due for such Calendar Quarter;

(b) each Party will report to the other Party within [***] after the end of each Calendar Quarter commencing with the Calendar Quarter in which the First Commercial Sale in the Profit Share Territory of a Shared Product occurs, the elements of the Net Profits and Net Losses calculation, including Net Sales (and the calculation thereof showing deductions taken with respect thereto) and Allowable Expenses incurred by such Party during such Calendar Quarter. [***]. Within [***] after receipt of such reports, Licensee will provide to Relay a consolidated financial statement setting forth the Net Profits and Net Losses for the Calendar Quarter. The following remittances will be paid as set forth below after Licensee has provided the consolidated financial statement:

(c) if there is a Net Profit for a Shared Product in such Calendar Quarter, then Licensee will pay to Relay a reconciling payment amount equal to Relay's portion of the Net Profit for such Calendar Quarter within [***] after providing the consolidated financial statement to Relay. An example of a Net Profit and corresponding reconciling payment calculation is set forth on Schedule 11.4.1; or

(d) if there is a Net Loss for a Shared Product in such Calendar Quarter, then Licensee will invoice Relay for the amounts due to Licensee as a result of reconciliation. Payment by Relay will be due [***] after receiving such an invoice from Licensee. An example of a Net Loss and corresponding reconciling payment calculation is set forth on Schedule 11.4.1.

11.4.2 FTE Records and Calculations. Licensee will record and account for its FTE effort to the extent that such FTE efforts are included in Allowable Expenses. Licensee will allocate and maintain records of FTE effort incurred by it in the same manner as used for other products developed by Licensee.

11.5 Additional Milestone Payments

11.5.1 Development/Commercial Milestones for Lead Royalty Products Outside the Opt-In Term. Subject to Section 11.5.2, in partial consideration of the licenses and other rights granted to Licensee hereunder and subject to the terms and conditions set forth in this Agreement, Licensee will pay to Relay the non-refundable, non-creditable one-time milestone payments set forth in Table 11.5.1 (each, a "**Development/Commercial Milestone Payment**") following the first achievement by or on behalf of Licensee (including by any of its Affiliates or any Licensee Sublicensee) of each of the milestone events by a Lead Royalty Product in the Territory (each, a "**Development/Commercial Milestone**") which Lead Royalty Product is (a) Covered by a Development Milestone Composition of Matter Claim in the case of Development/Commercial Milestones 1 and 2 or (b) Covered by a Composition of Matter Claim in the case of Development/Commercial Milestones 3, 4 and 5. [***]. Each of the Development/Commercial Milestone Payments set forth in this Section 11.5.1 is payable only upon the first achievement of the corresponding Development/Commercial Milestone [***] to achieve such Development/Commercial Milestone, and none of the Development/Commercial Milestone Payments will be payable more than once regardless of how many times the Development/Commercial Milestone is achieved. [***].

Table 11.5.1:

Number	Development/ Commercial Milestone	[***]			[***]	[***]
		[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]

[***].

11.5.2 Development/Commercial Milestones for Lead Royalty Products During the Opt-In Term. During the Opt-In Term, the Development/Commercial Milestones and Development/Commercial Milestone Payments will not apply and in lieu thereof, in partial consideration of the licenses and other rights granted to Licensee hereunder and subject to the terms and conditions set forth in this Agreement, Licensee will pay to Relay the non-refundable, non-creditable one-time milestone payments set forth in Table 11.5.2 (each, an "**Opt-In Term Development/Commercial Milestone Payment**") following the first achievement by or on behalf of Licensee (including by any of its Affiliates or any Licensee Sublicensee) of each of the milestone events by a Lead Royalty Product in the Royalty Territory (each, an "**Opt-In Term Development/Commercial Milestone**") which Lead Royalty Product is Covered by a Composition of Matter Claim. [***].

Table 11.5.2:

Number	Opt-In Term Development/ Commercial Milestone	[***]			[***]	[***]
		[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]

[***].

11.5.3 Development/Commercial Milestones for Back-Up Products at Anytime. In partial consideration of the licenses and other rights granted to Licensee hereunder and subject to the terms and conditions set forth in this Agreement, Licensee will pay to Relay the non-refundable, non-creditable one-time milestone payments set forth in Table 11.5.3 (each, a "**Back-Up Development/Commercial Milestone Payment**") following the first achievement by or on behalf of Licensee (including any of its Affiliates or any Licensee Sublicensee) of each of the milestone events by a Back-Up Product in the Territory (each, a "**Back-Up Development/Commercial Milestone**") which Back-Up Product is (a) Covered by a Development Milestone Composition of Matter Claim in the case of Back-Up Development/Commercial Milestones 1 and 2 or (b) Covered by a Composition of Matter Claim in the case of Back-Up Development/Commercial Milestones 3, 4 and 5, but solely in the event that a Back-Up Product achieves the corresponding Back-Up Development/Commercial Milestone prior to achievement of the corresponding Development/Commercial Milestone by a Lead Royalty Product (for purposes of this Section 11.5.3 the Development/Commercial Milestone will be deemed to have been achieved by a Shared Product if the Development/Commercial Milestone would have been achieved and paid to Relay for the applicable Lead Product pursuant to Section 11.5.1 had the Lead Product been a Lead Royalty Product and not a Shared Product at the time of achievement) or achievement of the corresponding Opt-In Development/Commercial Milestone by a Lead Royalty Product. [***]. Each of the Back-Up Development/Commercial Milestone Payments set forth in this Section 11.5.3 are payable only upon the first achievement of the corresponding Back-Up Development/Commercial Milestone [***], to achieve such Back-Up Development/Commercial Milestone, and none of the Back-Up Development/Commercial Milestone Payments will be payable more than once regardless of how many times the Back-Up Development/Commercial Milestone is achieved. [***]

Table 11.5.3:

Number	Back-Up Development/ Commercial Milestone	[***]			[***]	[***]
		[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]

[***].

11.5.4 Sales Milestones for Lead Royalty Products Outside the Opt-In Term. Subject to Section 11.5.5, in partial consideration of the licenses and other rights granted to Licensee hereunder and subject to the terms and conditions set forth in this Agreement, Licensee will pay to Relay the non-refundable, non-creditable one-time milestone payments set forth in Table 11.5.4 (each, a "**Sales Milestone Payment**") upon the first achievement of the aggregated annual Net Sales thresholds set forth in Table 11.5.4 by a Lead Royalty Product (each, a "**Sales Milestone**") which Lead Royalty Product is Covered by a Composition of Matter Claim. Multiple Sales Milestone Payments may be payable by Licensee within a given Calendar Year in the event that more than one Sales Milestone is achieved during such Calendar Year. By way of example,

if in the first Calendar Year in which Net Sales for a given Lead Royalty Product first exceed the Net Sales threshold set forth as Sales Milestone 1, and the Net Sales for the same or another Lead Royalty Product also exceed the Net Sales threshold set forth as Sales Milestone 2, then Licensee will pay Sales Milestone 1 and Sales Milestone 2 simultaneously. Notwithstanding the foregoing, any Sales Milestone Payments pursuant to this Section 11.5.4 will be reduced by the amount of Opt-In Sales Milestone Payments made pursuant to Section 11.5.5, and Relay will not be eligible for any Sales Milestone for which the equivalent amount of Opt-In Sales Milestone Payments have already been paid. [***].

Table 11.5.4

Number	Sales Milestone	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

11.5.5 Sales Milestones for Lead Royalty Products during the Opt-In Term. During the Opt-In Term, the Sales Milestones and Sales Milestones Payments set forth in Section 11.5.4 will not apply and in lieu thereof, in partial consideration of the licenses and other rights granted to Licensee hereunder and subject to the terms and conditions set forth in this Agreement, Licensee will pay to Relay the non-refundable, non-creditable one-time milestone payments set forth in Table 11.5.5 (each, an "**Opt-In Sales Milestone Payment**") upon the first achievement of the aggregated annual Net Sales thresholds set forth in Table 11.5.5 by a Lead Royalty Product in the Royalty Territory (each, an "**Opt-In Sales Milestone**") which Lead Royalty Product is Covered by a Composition of Matter Claim. Multiple Opt-In Sales Milestone Payments may be payable by Licensee within a given Calendar Year in the event that more than one Opt-In Sales Milestone is achieved during such Calendar Year. By way of example, if in the first Calendar Year in which Net Sales for a given Lead Royalty Product first exceed the Net Sales threshold set forth as Opt-In Sales Milestone 1, and the Opt-In Net Sales for the same or another Lead Royalty Product also exceed the Net Sales threshold set forth as Opt-In Sales Milestone 2, then Licensee will pay Opt-In Sales Milestone 1 and Opt-In Sales Milestone 2 simultaneously. Each of the Opt-In Sales Milestone Payments set forth in this Section 11.5.5 is payable only upon the first achievement of the corresponding Opt-In Sales Milestone by the first Lead Royalty Product to achieve such Opt-In Sales Milestone, and none of the Opt-In Sales Milestone Payments will be payable more than once regardless of how many times the Opt-In Sales Milestone is achieved. [***].

Table 11.5.5:

Number	Opt-In Sales Milestone	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

11.5.6 Sales Milestones for Back-Up Products at Anytime. In partial consideration of the licenses and other rights granted to Licensee hereunder and subject to the terms and conditions set forth in this Agreement, Licensee will pay to Relay the non-refundable, non-

creditable one-time milestone payments set forth in Table 11.5.6 (each, a "**Back-Up Sales Milestone Payment**") upon the first achievement of the aggregated annual Net Sales thresholds set forth in Table 11.5.6 by a Back-Up Product (each, a "**Back-Up Sales Milestone**"), which Back-Up Product is Covered by a Composition of Matter Claim but solely in the event that a Back-Up Product achieves the corresponding Back-Up Sales Milestone prior to achievement or deemed achievement of the corresponding Sales Milestone by a Lead Royalty Product (for purposes of this Section 11.5.6 the Sales Milestone will be deemed to have been achieved by a Shared Product if the Sales Milestone would have been achieved and paid to Relay for the applicable Lead Royalty Product pursuant to Section 11.5.4 had the Lead Product been a Lead Royalty Product and not a Shared Product at the time of achievement) or achievement of the corresponding Opt-In Sales Milestone by a Lead Royalty Product. [***] [***]

Table 11.5.6

Number	Back-Up Sales Milestone	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

11.5.7 Payment Terms for Milestone Payments.

(a) Licensee will provide Relay with written notice of achievement of any Development/Commercial Milestone, Opt-In Development/Commercial Milestone or Back-Up Development/Commercial Milestone within [***] after Licensee's confirmation of the achievement thereof and will make the corresponding payment of the Development/Commercial Milestone Payment, Opt-In Development/Commercial Milestone Payment or Back-Up Development/Commercial Milestone Payment, as applicable, within [***] after receipt of an invoice from Relay for the corresponding payment.

(b) As part of the Calendar Quarter royalty reports delivered pursuant to Section 11.7, Licensee will provide Relay with written notice of achievement of any Sales Milestone, Opt-In Sales Milestone or Back-Up Sales Milestone and Licensee will pay to Relay the applicable Sales Milestone Payment(s), Opt-In Sales Milestone Payment(s) or Back-Up Sales Milestone Payment(s) within [***] after receipt of an invoice from Relay regarding the achievement of such Sales Milestone, Opt-In Sales Milestone or Back-Up Sales Milestone.

11.6 Royalties

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11.6.1 Royalties for Lead Royalty Products Outside the Opt-In Term. Subject to Section 11.6.2, in partial consideration of the licenses and other rights granted to Licensee hereunder and subject to the terms and conditions set forth in this Agreement, during the applicable Royalty Term, on a Lead Royalty Product-by-Lead Royalty Product and country-by-country basis throughout the Territory, Licensee will pay to Relay royalties on the Net Sales in a given Calendar Year of each Lead Royalty Product that is Covered by a Valid Claim under a Relay Royalty Patent at the rates set forth in Table 11.6.1. Following the expiration of a particular Royalty Term with respect to a given country and Lead Royalty Product, the licenses to Licensee set forth in Article 12 will be perpetual, fully paid-up and royalty-free with respect to such Lead Royalty Product in

such country. The obligation to pay royalties will be imposed only once with respect to the same unit of Lead Royalty Product sold by Licensee, its Affiliate or Licensee Sublicensees.

Table 11.6.1

Portion of Aggregate Net Sales	[***]
[***]	[***]
[***]	[***]
[***]	[***]

11.6.2 Royalties for Lead Royalty Products During the Opt-In Term. During the Opt-In Term, the royalties set forth in Section 11.6.1 will not apply and in lieu thereof, in partial consideration of the licenses and other rights granted to Licensee hereunder and subject to the terms and conditions set forth in this Agreement, during the applicable Royalty Term, on a Lead Royalty Product-by-Lead Royalty Product and country-by-country basis throughout the Royalty Territory, Licensee will pay to Relay royalties on the Net Sales in a given Calendar Year in the Royalty Territory of each Lead Royalty Product that is Covered by a Valid Claim under a Relay Royalty Patent at the rates set forth in Table 11.6.2. Following the expiration of a particular Royalty Term with respect to a given country and Lead Royalty Product, the licenses to Licensee set forth in Article 12 will be perpetual, fully paid-up and royalty-free with respect to such Lead Royalty Product in such country. The obligation to pay royalties will be imposed only once with respect to the same unit of Lead Royalty Product sold by Licensee, its Affiliate or Licensee Sublicensees.

Table 11.6.2

Portion of Aggregate Net Sales in the Royalty Territory	[***]
[***]	[***]
[***]	[***]
[***]	[***]

For the avoidance of doubt, (a) during the Opt-In Term, aggregate Net Sales and royalties will be calculated and payable solely with respect to Net Sales of Lead Royalty Products in the Royalty Territory pursuant to this Section 11.6.2; and (b) outside of the Opt-In Term, aggregate Net Sales and royalties will calculated and payable with respect to Net Sales and Lead Royalty Products throughout the Territory pursuant to Section 11.6.1.

11.6.3 Royalties for Back-Up Products at Anytime. In partial consideration of the licenses and other rights granted to Licensee hereunder and subject to the terms and conditions set forth in this Agreement, during the applicable Royalty Term, on a Back-Up Product-by-Back-Up Product and country-by-country basis throughout the Territory, Licensee will pay to Relay royalties on the Net Sales in a given Calendar Year of each Back-Up Product that is Covered by a Valid Claim under a Relay Royalty Patent at the rates set forth in Table 11.6.3. Following the expiration of a particular Royalty Term with respect to a given country and Back-Up Product, the licenses to Licensee set forth in Article 12 will be perpetual, fully paid-up and royalty-free with respect to such Back-Up Product in such country. The obligation to pay royalties will be imposed only once with respect to the same unit of Back-Up Product sold by Licensee, its Affiliate or Licensee Sublicensees.

Table 11.6.3

Portion of Aggregate Net Sales	[***]
[***]	[***]
[***]	[***]
[***]	[***]

11.6.4 Third Party Agreements; Anti-Stacking.

(a) Relay will have the exclusive right to negotiate and enter into any agreement to obtain a license or otherwise acquire any intellectual property rights from a Third Party for Patents or Know-How [***]. Relay will be responsible for all consideration due to a Third Party in connection with Relay or its Affiliates in-licensing or otherwise acquiring any intellectual property rights under this Section 11.6.4(a).

(b) Licensee will have the exclusive right to negotiate and enter into any agreement to obtain a license or otherwise acquire any intellectual property rights from a Third Party for Patents or Know-How [***] (such other compounds or products, "**Licensee Pipeline Compounds**") [***]. Licensee will be responsible for all consideration due to a Third Party in connection with Licensee or its Affiliates in-licensing or otherwise acquiring any intellectual property rights under this Section 11.6.4(b).

(c) After the Effective Date, if either Party identifies any Patents or Know-How of a Third Party that is not included in the Relay IP or Licensee IP [***], such Party shall promptly notify the other Party of the existence of such Third Party Patents or Know-How.

(d) Licensee will have the exclusive right to negotiate and enter into an agreement to obtain a license or otherwise acquire any intellectual property rights from a Third Party for Patents or Know-How [***] (a "**Collaboration In-License**"), provided that Licensee will keep Relay reasonably informed regarding the progress of negotiating any such agreement.

(e) Relay will have the first right to negotiate and enter into an agreement to obtain a license or otherwise acquire any intellectual property rights from a Third Party for any Patents or Know-How Controlled by a Third Party arising out of any agreement between Relay and any Third Party existing as of or prior to the Effective Date and that is necessary or reasonably useful to Research, Develop, Manufacture or Commercialize any Licensed Candidate or Licensed Product, including in any Licensee Combination or any Relay Pipeline Combination ("**Prior Agreement Third Party IP**"), provided that [***]. If Relay notifies Licensee that it declines to negotiate and enter into an agreement to obtain a license to or otherwise acquire such Prior Agreement Third Party IP, or fails to enter into such agreement or acquisition approved by Licensee within [***] after notice of the Prior Agreement Third Party IP pursuant to Section 11.6.4(c), Licensee will have the right to negotiate and enter into any such agreement. Regardless of the Party negotiating and entering into any such agreement to obtain a license or otherwise acquire any intellectual property rights from a Third Party for Prior Agreement Third Party IP, Relay shall be solely responsible for all payments under such agreement to obtain such license or acquire such intellectual property rights.

(f) With respect to payments under a Collaboration In-License during the Term of this Agreement for a license under any Patents [***] ("**Shared Collaboration In-License Payments**") (i) such Shared Collaboration In-License Payments will be included in Development Costs or Allowable Expenses, to the extent consistent with the definitions thereof and (ii) any Shared Collaboration In-License Payments that are not Development Costs or Allowable Expenses will be [***] in accordance with Section 11.5.1, 11.5.2, 11.5.4, 11.5.5, 11.6.1 or 11.6.2, in accordance with Section 11.6.4(g).

(g) Licensee may deduct [***] (collectively "**Deductible Third Party IP Payments**") from any of the milestone payments otherwise payable to Relay under Sections 11.5.1, 11.5.2, 11.5.4 and 11.5.5 in an amount equal to up to [***] of such milestone payments and from any royalty payments under Sections 11.6.1 and 11.6.2 in a given period in an amount equal to up to [***] of such royalty payments on a Lead Product-by-Lead Product basis in the applicable country, such [***] limit to be calculated after applying Sections 11.6.5 and 11.6.6. For clarity, Licensee may carry forward to subsequent periods any Deductible Third Party IP Payments amounts that are not fully repaid to Licensee pursuant to the foregoing deductions in any period.

11.6.5 No Valid Claim. On a Licensed Product-by-Licensed Product and country-by-country basis, if during any portion of the Royalty Term for a given Licensed Product in a given country in the Royalty Territory or Territory, as applicable, no [***] Claim Covers the Licensed Product in the country of sale, then the royalty rate that would otherwise be owed and payable under Section 11.6, in each case, with respect to Net Sales of such Licensed Product in such country will be reduced by [***] for the remainder of such Royalty Term.

11.6.6 Generic Entry. On a Licensed Product-by-Licensed Product and country-by-country basis, if during any portion of the Royalty Term for a given Licensed Product in a given country in the Royalty Territory or Territory, as applicable, there is an entry of a Licensed Product sold by a Compulsory Sublicensee, a Competitive Product sold by Relay, its Affiliates or Relay Sublicensees or any Generic Product, in each case in a given country in the Territory when such Licensed Product is sold in such country by Licensee, its Affiliates or Licensee Sublicensees and (a) there has been a decline of the Sales of the applicable Licensed Product in such country greater than [***] of the average quarterly Sales of Licensed Product in such country [***] before the entry of such Licensed Product sold by a Compulsory Sublicensee, Generic Product or Competitive Product in such country, then the royalty rate that would otherwise be owed and payable under Section 11.6.1, 11.6.2 or 11.6.3 (as applicable), in each case, with respect to Net Sales of such Licensed Product in such country will be reduced [***] for [***] of the Royalty Term for such Licensed Product in such country or, if sooner, until further royalty reduction applies pursuant to clause (b) or (c) below, (b) there has been a decline of the Sales of the applicable Licensed Product in such country [***] of the average quarterly Sales of Licensed Product in such country [***] before the entry of such Licensed Product sold by a Compulsory Sublicensee, Generic Product or Competitive Product in such country, then the royalty rate that would otherwise be owed and payable under Section 11.6.1, 11.6.2 or 11.6.3 (as applicable), in each case, with respect to Net Sales of such Licensed Product in such country will be reduced by [***] for [***] of the Royalty Term for such Licensed Product in such country or, if sooner, until further royalty reduction applies pursuant to clause (c) below, or (c) there has been a decline of the Sales of the applicable Licensed Product in such country greater than [***] of the average quarterly Sales of Licensed Product in such country [***] before the entry of such Licensed Product sold by a Compulsory Sublicensee,

Generic Product or Competitive Product in such country, then the royalty rate that would otherwise be owed and payable under Section 11.6.1, 11.6.2 or 11.6.3, in each case, with respect to Net Sales of such Licensed Product in such country will be reduced to [***] after which time the license for such Licensed Product in such country shall thereafter be fully paid-up and irrevocable for such Licensed Product in such country for so long as such Licensed Product is sold in such country. The royalty reductions in this Section 11.6.6 and the royalty reductions in Section 11.6.5 taken together shall not exceed [***] reduction for a Licensed Product in a country, except where clause (c) of this Section 11.6.6 applies, in which case the royalty rate will be reduced to [***] and the license for such Licensed Product in such country shall thereafter be fully paid-up and irrevocable for such Licensed Product in such country for so long as such Licensed Product is sold in such country. For the avoidance of doubt, royalty reductions pursuant to Section 11.6.4 will be applied to the royalty as reduced pursuant to Section 11.6.5 and 11.6.6.

11.7 Royalty Payments and Reporting

. Licensee will calculate all amounts payable to Relay pursuant to Section 11.6 at the end of each Calendar Quarter and will pay to Relay the royalty amounts due with respect to a given Calendar Quarter within [***] after the end of such Calendar Quarter. Each payment of royalties due to Relay will be accompanied by a statement of the amount of Sales and Net Sales of each Licensed Product in each country in the Royalty Territory or Territory, as applicable, during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars) and a detailed calculation of the amount of royalty payment due on such Net Sales for such Calendar Quarter (including all deductions and reductions).

11.8 Opt-Out.

11.8.1 In the event that Relay exercises its Opt-Out Right, all Shared Products will automatically become Lead Royalty Products as of the effective date of such exercise and, subject to the remainder of this Section 11.8, Section 11.5.1 will apply and Section 11.5.2 will not apply, Section 11.5.4 will apply and Section 11.5.5 will not apply, and Section 11.6.1 will apply and Section 11.6.2 will not apply.

11.8.2 In addition to the foregoing in the case of an exercise by Relay of its Opt-Out Right pursuant to Section 4.2.1 (but expressly excluding any forced exercise of such Opt-Out Right by Licensee pursuant to Section 4.2.2), the royalty rates set forth in Table 11.6.1 will be increased by [***].

11.9 Relay Pipeline Compounds; Relay Pipeline Products. Except as set forth in Section 7.2.3, in no event will Relay owe Licensee any milestones, royalties or other payments with respect to the retained rights under the Relay IP or license under Licensee IP to Develop and co-promote, in accordance with this Agreement and any applicable Coordinated Promotion Agreement, the Relay Pipeline Combination Eligible Licensed Products for Combination Use in Relay Pipeline Combinations.

11.10 [***].

11.11 Other Amounts Payable. With respect to any amounts owed under this Agreement by a Party to the other Party for which no other invoicing and payment procedure is specified in this Agreement, the Party owing such payment obligation will provide to the other Party an

invoice, together with reasonable supporting documentation, for such amounts owed and such other Party will pay any undisputed amounts within [***] after receipt of the invoice, and will pay any disputed amounts owed by such other Party within [***] of final resolution of the Dispute.

11.12 Additional Payment Terms

.

11.12.1 Method of Payment. All payments to a Party under this Agreement will be made by deposit of Dollars in the requisite amount to such bank account as such Party may from time to time designate by notice to the other Party.

11.12.2 Invoices. All invoices that are required or permitted hereunder to be sent to Licensee shall be in writing and sent by Relay to Licensee's Alliance Manager at [***] with a copy to [***] or such other address as Licensee may later provide.

11.12.3 Currency. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), Licensee will convert any amount expressed in a foreign currency into Dollars equivalents using its, its Affiliate's or the applicable Licensee Sublicensee's standard conversion methodology consistent with Accounting Standards.

11.12.4 Blocked Currency. Notwithstanding Section 11.12.1 or Section 11.12.2, in the event that Licensee (or its Affiliate or Sublicensee) is prohibited by Applicable Law from making any payment (or portion thereof) to Relay under this Agreement with respect to any given country, such payments shall continue to accrue in such country, but Licensee shall not be obligated to make such payments until such time as payment may be made through reasonable, lawful means or methods that may be available, as Licensee shall reasonably determine, and at the time of payment shall pay such accrued royalties in Dollars using the actual exchange rate which is used to remove such sales proceeds from such country.

11.12.5 Late Payments. If any payment due to either Party under this Agreement is not paid when due, then the payor Party with respect thereto will pay simple interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) equal to [***].

11.12.6 No Double Counting. Notwithstanding anything to the contrary contained herein, no cost or expense will be included in calculations of amounts due under this Agreement if inclusion therein would result in a duplication or double-counting of the same cost or expense hereunder.

11.13 Taxes

.

11.13.1 General. Except as expressly set out in this Agreement, a Party making payments to the other Party under this Agreement will make such payments in full without set-off or counterclaim and without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by Applicable Law in effect at the time of payment.

11.13.2 Taxes on Income. Each Party will be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement.

11.13.3 Withholding. Licensee may withhold from payments due to Relay amounts for payment of any withholding tax that is required by Applicable Law to be paid to any taxing authority with respect to such payments. Licensee will give proper evidence, as may be reasonably requested by Relay, from time to time, as to the payment of any such tax. Notwithstanding the foregoing, if Licensee assigns its rights and obligations hereunder to an Affiliate or Third Party pursuant to Section 18.3 or sublicenses any intellectual property licensed to Licensee hereunder, and if Licensee or such Affiliate or Third Party is required by Applicable Law to withhold any additional taxes from or in respect of any amount payable under this Agreement as a result of such assignment or sublicense, then any such amount payable under this Agreement will be increased to take into account the additional taxes withheld as may be necessary so that, after making all required withholdings (including withholdings on the withheld amounts), Relay receives an amount equal to the sum it would have received had no such withholding been made; provided, however, that Licensee will have no obligation to pay any additional amount to the extent that the withholding tax would not have been imposed but for (a) the failure by Relay to take advantage of an otherwise available exemption from or reduction in the rate of withholding tax under any applicable income tax convention between the United States and the jurisdiction in which such Affiliate or Third Party is domiciled, or (b) the assignment by Relay of its rights under this Agreement or any redomiciliation of Relay outside of the United States or any public offering or any other bona fide capital raising event, public or private, a reorganization, spin-out, merger, or consolidation. Notwithstanding the foregoing, if Licensee has an obligation to pay additional amounts to account for withholding taxes, it will be entitled to a full amount of any foreign tax credit attributable to Relay if and when realized in cash by Relay as a result of such payment.

11.13.4 Cooperation. The Parties will cooperate with respect to all documentation required by any taxing authority, the preparation of any tax returns, or reasonably requested by either Party to secure a reduction in the rate of applicable withholding taxes.

11.13.5 Indemnification for Withholding. Subject to Section 11.13.3, if the applicable paying Party had a duty to withhold taxes in connection with any payment it made to the other Party under this Agreement but such paying Party failed to withhold, and such taxes were assessed against and paid by such paying Party, then the other Party will indemnify and hold harmless such paying Party from and against such taxes (including interest, but not including any related penalties). If such paying Party makes a claim under this Section 11.13.5, it will comply with the obligations imposed by Section 11.13.4 as if such paying Party had withheld taxes from a payment to the other Party.

11.13.6 Tax Treatment. Except as set forth in the following sentence, Relay and Licensee agree that, consistent with Section 18.19, this Agreement is not intended to constitute a partnership for any purpose, including U.S. federal income and other applicable tax purposes. Relay and Licensee agree to cooperate in good faith to determine the tax treatment of the exercise of the Opt-In Right in the Profit Share Territory, including determining treatment as a partnership for U.S. federal income and other applicable tax purposes, and Relay and Licensee will negotiate in good faith to enter into any agreements advisable or necessary to implement such tax treatment.

11.14 Financial Records

. Each Party will, and will cause its Affiliates and Sublicensees to, keep complete and accurate books and records pertaining to amounts due under this Agreement in sufficient detail to calculate all amounts payable hereunder and to verify compliance with its

obligations under this Agreement. Such books and records will be retained by each Party and its Affiliates and Sublicensees for [***] after the end of the period to which such books and records pertain.

11.15 Audit Rights. At the request of Relay, Licensee will, and will cause its Affiliates and Licensee Sublicensees to, permit a certified independent public accountant designated by Relay and reasonably acceptable to Licensee, at reasonable times and upon reasonable notice, to audit the books and records maintained by Licensee (or its Affiliate or Licensee Sublicensee, as applicable) pursuant to this Agreement to ensure the accuracy of all reports and payments made hereunder. Such books and records will be available to the auditor during regular business hours at such place or places where such books and records are customarily kept. Such examinations may not (a) be conducted for any Calendar Quarter more than [***] after the end of such Calendar Quarter, (b) be conducted more than once in any [***] period or (c) be repeated for any Calendar Quarter. Except as provided below, the cost of this audit will be borne by Relay, unless the audit reveals an underreporting of amounts due to, or an overreporting of amounts due from, Relay of at least [***]. If such audit concludes that (A) the amount Licensee paid to Relay for a given Calendar Quarter exceeded the amount that was payable to Relay, then at Licensee's option, (1) Relay will reimburse Licensee for such undisputed variance within [***] after the date on which such audit is completed or (2) Licensee will have the right to credit such excess amounts paid towards future payments owed to Relay under this Agreement, or (B) the amount Licensee paid to Relay for a given Calendar Quarter was less than the amount that was payable to Relay, Licensee will pay Relay for such undisputed variance within [***] after the date on which such audit is completed. Relay will treat all information subject to review under Section 11.14 and this Section 11.15 in accordance with the confidentiality provisions of Article 13.

ARTICLE 12.
LICENSES; INTELLECTUAL PROPERTY

12.1 Licenses.

12.1.1 Relay.

(a) Relay hereby grants to Licensee and its Affiliates an exclusive, sublicensable (through multiple tiers, subject to the provisions of Section 12.2), non-transferrable (except as set forth in Section 18.3) license under the Relay IP to Research, Develop, Manufacture and Commercialize the Licensed Candidates and Licensed Products, including Combination Use of such Licensed Candidate and Licensed Products with other compounds or products, in the Field in the Territory; provided that Relay and its Affiliates retain rights under the Relay IP to perform its obligations hereunder or Develop, and co-promote in accordance with this Agreement and any applicable Coordinated Promotion Agreement, the Relay Pipeline Combination Eligible Licensed Products solely for Combination Use in Relay Pipeline Combinations and subject to Section 12.2, and the right to grant licenses (and further sublicenses) with respect thereto and to conduct the activities permitted under Section 9.1.3. For the avoidance of doubt the license granted to Licensee does not include the right to Research, Develop, Manufacture or Commercialize Relay Pipeline Compounds or Relay Pipeline Products.

(b) With respect to any Back-Up Compounds, upon determination by Licensee that it will commence Development of a Back-Up Compound, Licensee shall provide a written notice to

Relay of such determination, and shall identify the Back-Up Compound, [***], and the Relay Patent that discloses or claims such Back-Up Compound. [***].

12.1.2 Relay hereby grants to Licensee a non-exclusive, royalty-free, fully paid-up, sublicensable (through multiple tiers, subject to the provisions of Section 12.2), non-transferrable (except as set forth in Section 18.3) license, under the Relay IP for Licensee's internal research and pre-clinical development purposes in the Field and in the Territory. It is understood and agreed that no commercial license is granted by Relay under this Section 12.1.2. The license granted pursuant to this Section 12.1.2 will terminate on expiration or termination of this Agreement; provided that (a) [***] and (b) Licensee and its Affiliates shall be entitled to use for any purpose thereafter in the Field and in the Territory the residual information retained by personnel of Licensee and its Affiliates that had access to Relay Know-How or other Relay Confidential Information. As used herein, "residual information" means Know-How or other Confidential Information that are retained in the memories of individuals without the aid of any document or other recorded or stored information containing Relay Know-How or other Relay Confidential Information.

12.1.3 Licensee hereby grants to Relay a non-exclusive, sublicensable (through multiple tiers, subject to the provisions of Section 12.2), non-transferable (except as set forth in Section 18.3), worldwide, royalty-free license under the Licensee IP to perform its obligations hereunder and Develop and co-promote in accordance with this Agreement any applicable Coordinated Promotion Agreement, the Relay Pipeline Combination Eligible Licensed Products solely for Combination Use in Relay Pipeline Combinations.

12.1.4 Relay shall further have such rights as are granted to it in the Supply Agreement or pursuant to Section 16.9.

12.2 Sublicensing

. Each Party will have the right to grant sublicenses, or in the case of Relay, licenses under the rights retained by Relay, under the rights granted to or retained by it, as applicable, under Section 12.1, through multiple tiers, to (a) any Affiliate and (b) in the case of Licensee, any Third Party and (c) in the case of Relay, (i) any Third Party that is a strategic collaborator (but not a CRO or CMO) with respect to a Relay Pipeline Combination (a "**Relay Combination Collaborator**") and (ii) any other Third Party with Licensee's prior written consent. As between the Parties, each Party will remain at all times fully liable for any actions or omissions by its Sublicensees that may be a breach of this Agreement, subject to the last sentence of Section 16.3. Each sublicense granted under this Section 12.2 will be consistent with the terms and conditions of this Agreement, and with respect to sublicenses to Third Party Subcontractors, will be subject to Section 8.1.4. Relay will give Licensee written notice of entering into an agreement with a Relay Combination Collaborator.

12.3 Rights Retained by the Parties

. For purposes of clarity, each Party retains all rights under Know-How, Patents and other intellectual property, controlled by such Party not expressly granted to the other Party pursuant to this Agreement.

12.4 No Implied Licenses

. Except as explicitly set forth in this Agreement, neither Party will be deemed by estoppel, implication or otherwise to have granted the other Party any license or other right to any Know-How, Patents or other intellectual property of such Party. Neither Party nor any of its Affiliates will use or practice any Know-How or Patents licensed or provided to such

Party or any of its Affiliates outside the scope of or otherwise not in compliance with the rights and licenses granted to such Party and its Affiliates under this Agreement.

12.5 Bankruptcy

. All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined in Section 101 of such Code. Each Party, as licensee, may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that, if a Party elects to retain its rights as a licensee under any Bankruptcy Code, such Party will be entitled to complete access to any technology licensed to it hereunder and all embodiments of such technology. Such embodiments of the technology will be delivered to the licensee Party not later than: (a) the commencement of bankruptcy proceedings against the licensor, upon written request, unless the licensor elects to perform its obligations under this Agreement; or (b) if not delivered under Section 12.5(a), upon the rejection of this Agreement by or on behalf of the licensor, upon written request. Any agreements supplemental hereto will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code. As used herein, "**Bankruptcy Code**" means the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party or its assets.

12.6 Third Party Agreements.

12.6.1 Relay shall not provide the Lead Candidate to any Third Party, including any Third Party with whom Relay has an existing agreement, on or after the Effective Date. Promptly after the Effective Date, Relay will inform all Third Parties to whom Relay has previously provided the Lead Candidate pursuant to an existing agreement to discontinue use of the Lead Candidate [***]. The foregoing sentences of this Section 12.6.1 will not apply to (a) use of the Lead Candidate as permitted under Relay's agreement(s) with the Relay Phase Ia Trial CRO, (b) the use of the Lead Candidate by Relay, a Relay Combination Collaborator or Relay Subcontractor solely in connection with Relay's pre-clinical Development activities to support Relay Pipeline Combinations, or (c) use of the Lead Candidate as permitted under the Supply Agreement or pursuant to Section 16.9.

12.6.2 Promptly after the Effective Date, to the extent Relay does not already have such right under the applicable Existing Sponsored Research Agreement, Relay will use Commercially Reasonable Efforts to obtain the right to share data and reports received by Relay under each of the Existing Sponsored Research Agreements with Licensee and for Licensee to use such data and reports for Licensee's internal research purposes.

12.6.3 Relay shall be responsible for performing all obligations under each Existing Third Party Agreement (including any payment obligations), even if such obligations arise as a result of Licensee's (or an Affiliate's or Sublicensee's) activities in compliance with this Agreement.

(a) Except as could not reasonably be expected to have a materially adverse effect on the licenses or rights granted to Licensee hereunder or impose additional obligations on Licensee, during the Term, Relay shall maintain each Existing Third Party Agreement in full force and effect, in each case in accordance with its terms and conditions, and shall not (i) commit any acts or omissions that could cause a breach of or give rise to a right to terminate an Existing Third Party Agreement or (ii) amend or terminate an Existing Third Party

Agreement or exercise or waive any rights it may have under an Existing Third Party Agreement, in all cases, without the prior consent of Licensee. [***].

(b) In the event of any notice of breach by Relay given to Relay under any Existing Third Party Agreement, Relay shall immediately notify Licensee in writing and if Relay fails to cure such breach, Licensee shall have the right, but not the obligation, to cure such breach on behalf of Relay solely if the termination of such Existing Third Party Agreement could be reasonably expected to have a materially adverse effect on the licenses or rights granted to Licensee hereunder, and to offset any amounts incurred or paid by Licensee in connection with the cure of such breach against any amounts otherwise payable by Licensee to Relay under this Agreement until fully offset. In the event Relay receives notice of any breach by the other party of the applicable Existing Third Party Agreement in a manner that could be reasonably expected to have a material adverse effect Licensee's rights or obligations under this Agreement, Relay shall promptly notify Licensee in writing, and Relay shall take such actions as are reasonably requested by Licensee to enforce such Existing Third Party Agreement.

12.7 Intellectual Property.

12.7.1 Inventorship. Notwithstanding the provisions of Section 18.6, inventorship of any inventions (whether patentable or not), and associated Know-How created, conceived or generated by or on behalf of a Party or its Affiliates, whether solely or jointly with any Third Party (or with the other Party or its Affiliates), in the course of activities performed under this Agreement, will be determined by application of U.S. patent law pertaining to inventorship.

12.7.2 Relay. As between the Parties and subject to Section 12.7.4, Relay will retain all right, title and interest in and to all Relay IP, and no rights or licenses are granted to Licensee hereunder with respect to any Relay IP other than the licenses and rights granted to Licensee pursuant to this Article 12.

12.7.3 Licensee IP. As between the Parties and subject to Section 12.7.4, Licensee will retain all right, title and interest in and to all Licensee IP, and no rights or licenses are granted to Relay hereunder with respect to any Licensee IP other than the licenses and rights granted to Relay pursuant to this Article 12.

12.7.4 Joint Collaboration IP. As between the Parties, the Parties will each own an equal, undivided interest in all Joint Collaboration IP. Each Party will have the right to exploit the Joint Collaboration IP without a duty of seeking consent or accounting to the other Party.

12.7.5 Cooperation. Subject to Section 8.1.4, each Party will cause all Persons who perform activities for such Party under this Agreement to be under an obligation to assign their rights in any Know-How or Patents resulting therefrom to such Party, except where Applicable Law requires otherwise, and except in the case of governmental, not-for-profit and public institutions which have standard policies against such an assignment (in which case a suitable license, or right to obtain such a license, will be obtained). Without limiting (but subject to) the foregoing, each Party will cause its employees, consultants, sublicensees, agents and contractors to assign to such Party, such Person's right, title and interest in and to all Know-How or Patents resulting from activities under this Agreement, and intellectual property rights therein.

12.7.6 Disclosure of Joint IP. Each Party will promptly disclose to the other any Joint Collaboration Know-How created, conceived or generated during the Term, but no later than [***] after Licensee's or its Affiliate's intellectual property department receives written notice of such creation, conception or generation.

12.7.7 Trademarks. Licensee will have the sole right to determine and own the Trademarks used in connection with the Development, Manufacture and Commercialization of the Licensed Products on a worldwide basis.

12.8 Prosecution and Maintenance.

12.8.1 Relay Patents and Joint Collaboration Patents.

(a) Licensee will have the first right (but not the obligation), in its sole discretion and with counsel of Licensee's choice, to Prosecute and Maintain the Relay Patents and Joint Collaboration Patents (other than Relay Combination Patents). [***].

(i) Licensee shall have the right to allow any Relay Patent to lapse or become abandoned in any Core Country in which such Relay Patent is pending, so long as [***] Relay Patent in the same family has been granted and remains in force in such Core Country; provided that if Licensee intends to allow to lapse or abandon in any Core Country a Relay Patent that includes [***] the Lead Candidate, Relay shall have the rights set forth in Section 12.8.1(b);

(ii) Licensee shall have the right to allow any Relay Patent to lapse or become abandoned in all other countries other than the Core Countries even if no related Relay Patent in the same family has been granted in such country; and

(b) If Licensee intends to allow a Relay Patent to lapse or become abandoned, and only in such case where such lapse or abandonment is (A) in a Core Country in which [***] other Relay Patent in the same family has been granted and remains in force, (B) worldwide for the entire patent family to which such Relay Patent relates, or (C) such lapse or abandonment is in a Core Country and such Relay Patent includes [***] the Lead Candidate, then in any of the foregoing (A), (B) or (C), Licensee will provide reasonable prior written notice to Relay of such intention (which notice will, in any event, be given no less than [***] prior to the date for which lapse or abandonment will occur), and Relay will thereupon have the right (but not the obligation) to assume the Prosecution and Maintenance thereof, at Relay's cost and expense with counsel of Relay's choice, after prior written notice to Licensee.

(c) Relay will have the first right (but not the obligation), in its sole discretion and at its cost and expense with counsel of Relay's choice, to Prosecute and Maintain the Relay Combination Patents. Notwithstanding the foregoing, if Relay's strategy with respect to the Prosecution and Maintenance of any Relay Combination Patent could reasonably be expected to materially conflict with or negatively impact Licensee's strategy with respect to the Prosecution and Maintenance of Licensed Candidates and Licensed Products, including Licensee Combinations, Relay will notify Licensee and meet with Licensee a reasonable time prior to Relay's filing a patent application with respect to such Relay Combination Patent to discuss such strategy and attempt to resolve in good faith any such material conflict or negative impact,

including considering whether Relay's strategy can be modified to avoid any conflicts or negative impacts. [***].

(d) Relay will keep Licensee's outside patent counsel informed as to material developments with respect to the Prosecution and Maintenance of Generic Relay Combination Patents and other Relay Combination Patents [***]with compounds or products Directed to the Collaboration Target, including by providing Licensee's outside patent counsel with a copy of material communications to and from any patent authority regarding such Generic Relay Combination Patent or such other Relay Combination Patent, and by providing the drafts to Licensee's outside patent counsel of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for Licensee's outside patent counsel to review and comment thereon. Relay will consider in good faith the requests and suggestions of Licensee's outside patent counsel with respect to such drafts of Relay and with respect to strategies for filing and prosecuting the applicable Generic Relay Combination Patent or applicable other Relay Combination Patent. Notwithstanding the foregoing, Relay will promptly inform Licensee's outside patent counsel of any adversarial patent office proceeding or sua sponte filing, including a request for, or filing or declaration of, any interference, derivation proceeding, post-grant proceeding, opposition, post-grant proceeding or reexamination relating to the applicable Generic Relay Combination Patent or applicable other Relay Combination Patent. Relay will consult with Licensee's outside patent counsel and Relay will consider in good faith all comments, requests and suggestions provided by Licensee's outside patent counsel. Licensee will cause its outside counsel to not share with Licensee the foregoing information provided by Relay to Licensee's outside patent counsel under this Section (d), except if Licensee exercises its back-up rights as provided below. If Relay intends to allow a Generic Relay Combination Patent or another Relay Combination Patent [***] with compounds or products Directed to the Collaboration Target to lapse or become abandoned, then Relay will provide reasonable prior written notice to Licensee of such intention (which notice will, in any event, be given no later than [***] prior to the next deadline for any action that may be taken with respect to such Patent in such country), and (i) in the case of Generic Relay Combination Patents, Licensee will thereupon have the right (but not the obligation) to assume the Prosecution and Maintenance thereof, at Licensee's cost and expense with counsel of Licensee's choice and (ii) in the case of Relay Combination Patents other than Generic Relay Combination Patents [***] with compounds or products Directed to the Collaboration Target, to the extent it is possible, Licensee may file a continuing applications [***], which application would then constitute a Generic Relay Combination Patent for all purposes under this Agreement, except that with respect to Prosecution and Maintenance, Licensee will have the sole right (but not the obligation) to Prosecute and Maintain such Generic Relay Combination Patent at Licensee's cost and expense with counsel of Licensee's choice.

12.8.2 Cooperation. Each Party will provide the other Party all reasonable assistance and cooperation in the Prosecution and Maintenance efforts with respect to any Relay Patent or Joint Collaboration Patent, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution and taking all actions necessary to correct any error or mistake in inventorship. When a Party assumes the responsibilities for the Prosecution and Maintenance of a Patent under Section 12.8.1, the other Party will promptly transfer to such Party the patent prosecution files for such Patent and provide reasonable assistance

in the transfer of the prosecution responsibilities. The Party assuming such Prosecution and Maintenance responsibilities will have the right to engage its own counsel to do so.

12.8.3 CREATE Act/AIA. It is the intention of the Parties that this Agreement is a "joint research agreement" as that phrase is defined in the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. 103(c)(2)-(c)(3) (the "**CREATE Act**") or the Leahy-Smith America Invents Act of 2011, 35 U.S.C. 100(h) and 102(c)(1)(3) (the "**AIA**"). In the event that a Party intends to overcome a rejection of a claimed invention within the Relay Patents or Joint Collaboration Patents under this Agreement pursuant to the provisions of 35 USC § 102(c) or 35 USC § 103(c), such Party shall first obtain the prior written consent of the other Party. Following receipt of such written consent, such Party shall limit any amendment to the specification or statement to the patent office with respect to this Agreement to that which is strictly required by 35 USC § 102(c) or 35 USC § 103(c) and the rules and regulations promulgated thereunder and which is consistent with the terms and conditions of this Agreement. If the Parties agree that, in order to overcome a rejection of a claimed invention within the Relay Patents or Joint Collaboration Patents pursuant to the provisions of the CREATE Act or AIA, the filing of a terminal disclaimer is required or advisable, the Parties shall first agree on terms and conditions under which the patent application subject to such terminal disclaimer and the patent or application over which such application is disclaimed shall be jointly enforced, if and to the extent that the Parties have not previously agreed to such terms and conditions. To the extent applicable or necessary, Relay shall use Commercially Reasonable Efforts to obtain the prompt cooperation of DESRES in effectuating the objectives of this Section 12.8.3.

12.9 Enforcement

of Relay Patents and Joint Collaboration Patents.

12.9.1 Notice. If either Party learns of any actual or suspected infringement of any Relay Patent or Joint Collaboration Patent in the Field, in each case, such Party will promptly notify the other Party in writing and will provide such other Party with available evidence of such infringement, and following such notification, the Parties will confer.

12.9.2 Enforcement

(a) Infringement.

(i) Licensee will have the first right (but not the obligation) in its discretion to enforce any Patent within the Relay Patents or Joint Collaboration Patents against any infringement in the Field, including without limitation Competitive Infringement (which may include settlement or otherwise seeking to secure the abatement of such infringement) by counsel of its choice, in its own name, including the right to control the defense of any challenges to any such Relay Patent or Joint Collaboration Patent as a counterclaim in such infringement proceeding as well as the defense of declaratory judgment actions. Relay shall reasonably cooperate with Licensee in any infringement action pursuant to this Section 12.9. If Licensee finds it necessary or desirable for Relay to join Licensee as a party to any such claim, suit, or proceeding with respect to any such infringement, the Parties will cooperate to execute all papers and perform such acts as will be reasonably required for Relay to join such claim, suit, or proceeding.

(ii) If Licensee notifies Relay that Licensee declines to enforce any of the Relay Patents or Joint Collaboration Patents against any infringement in the Field or fails to commence an enforcement action with respect to any infringement of any of the Relay Patents or Joint Collaboration Patents under Section 12.9.2(a)(i) within [***] following delivery of notice pursuant to Section 12.9.1, Relay will thereupon have the right (but not the obligation) to enforce applicable Relay Patents or Joint Collaboration Patents against such infringement, at its own cost and expense (which may include settlement or otherwise seeking to secure the abatement of such infringement), by counsel of its choice, in its own name, including the right to control the defense of any challenges to any such Relay Patent or Joint Collaboration Patent as a counterclaim in such infringement proceeding as well as the defense of declaratory judgment actions, in each case after prior written notice to Licensee. For the avoidance of doubt, Relay shall have no right to take over enforcement of any Relay Patent or Joint Collaboration Patent against an infringement pursuant to this subclause (a)(ii) if Licensee is enforcing [***] Relay Patent or Joint Collaboration Patent or other Patent in the Licensee IP against such infringement. Relay shall further have no right to take over enforcement of any Relay Patent or Joint Collaboration Patent against an infringement pursuant to this subclause (a)(ii) if such infringement is a deemed infringement as a result of the filing of an ANDA by a Third Party with respect to a Licensed Product in the Field in the Territory with the Licensed Product as the reference product by any such Third Party. Licensee shall reasonably cooperate with Relay in any infringement action pursuant to this Section 12.9.2(a)(ii). If Relay finds it necessary or desirable for Licensee to join Relay as a party to any such claim, suit, or proceeding with respect to any such infringement, the Parties will cooperate to execute all papers and perform such acts as will be reasonably required for Licensee to join such claim, suit, or proceeding. During any such claim, suit, or proceeding with respect to any infringement of any 1971 Patent or Relay Combination Patent, Relay will keep Licensee regularly informed of the status and progress of such enforcement efforts and will reasonably consult with Licensee, including using reasonable efforts to take Licensee's comments into good faith consideration with respect to such infringement or the claim construction of any infringement claim in any such Patent.

(iii) Notwithstanding anything herein the contrary, Licensee's rights under this Section 12.9 with respect to Relay Combination Patents are limited to Generic Relay Combination Patents and Licensee has no rights under this Section 12.9 with respect to other Relay Combination Patents.

12.9.3 Cooperation. The Party not controlling any infringement action pursuant to Section 12.9.2(a) will reasonably cooperate with the controlling Party. A settlement or consent judgment or other voluntary final disposition of a suit with respect to any Relay Patents or Joint Collaboration Patent under Section 12.9.2(a) may be entered into without the consent of the non-controlling Party; provided, however, that any such settlement, consent judgment or other disposition of any action or proceeding by the controlling Party under Section 12.9.2(a) will not, without the prior written consent of the non-controlling Party (a) impose any liability or obligation on the non-controlling Party or any of its Affiliates or (b) conflict with or reduce the scope of the subject matter claimed in the applicable Relay Patent or Joint Collaboration Patent.

12.9.4 Costs and Recoveries.

(a) The Party enforcing any Patent under this Section 12.9 (the "**Enforcing Party**") will pay all costs and expenses incurred in connection with any action, suit or proceeding brought under Section 12.9.2(a).

(b) To the extent the enforcement of a Patent against any infringement pursuant to this Section 12.9 involves a Shared Product in the Profit Share Territory, then all costs and recoveries incurred or obtained pursuant to this Section 12.9.4 will be deemed to be Other Shared Expenses and included in the calculation of Net Profits and Net Losses in accordance with the Sharing Percentages pursuant to Section 11.3.1.

(c) Except as set forth in Section 12.9.4(b), all damages or other monetary awards recovered in any action, suit or proceeding brought under Section 12.9.2(a) to the extent related to any Relay Patent or Joint Collaboration Patent will be shared as follows:

(i) the amount of such recovery actually received will first be applied to Out-of-Pocket Costs incurred by each Party in connection with such action (including, for this purpose, a reasonable allocation of expenses of internal counsel); and

(ii) any remaining proceeds constituting direct or actual damages for acts of infringement will be paid to, or retained by, the Enforcing Party; provided that, if the Enforcing Party is Licensee, such amounts will be included in Net Sales for the Calendar Quarter in which such amounts are received by Licensee; and

(iii) any remaining proceeds constituting punitive or treble damages will be allocated between the Parties as follows: [***].

(d) Relay will retain all recoveries obtained by Relay with respect to Relay Combination Patents that are not Generic Relay Combination Patents.

12.10 Invalidity or Unenforceability Defenses or Actions.

12.10.1 Notice. During the Term of this Agreement, each Party will promptly notify the other Party in writing of any written assertion of invalidity or unenforceability of any Relay Patents or Joint Collaboration Patents by a Third Party, including any inter partes review, re-examinations, post-grant proceedings or other similar proceedings with respect to any Relay Patent or Joint Collaboration Patent, in each case, of which such Party becomes aware.

12.10.2 Defense.

(a) During the Term of this Agreement, Licensee will have the first right (but not the obligation) to defend and control the defense of the validity and enforceability of any Relay Patent or Joint Collaboration Patent (other than Relay Combination Patents), at its own cost and expense, subject to the remainder of this Section 12.10.2. With respect to any such action involving the validity or enforceability of any such Relay Patent or Joint Collaboration Patent, if Licensee finds it necessary or desirable for Relay to join Licensee as a party to any such action, Relay will, at Licensee's request and expense, join Licensee as a party to such suit; provided that, Relay will pay for counsel of its choosing if Relay chooses not to participate with Licensee's counsel; provided further that Licensee will retain control of the defense in such claim, suit, or

proceeding. With respect to 1971 Patents, Licensee will initially pay its costs and expense and all liabilities, damages, recoveries or settlement payments with respect to the defense of the relevant 1971 Patent and the Parties will thereafter will share any Licensee costs and expenses and liabilities, damages, recoveries, or settlement payments arising out of Licensee's defense of such 1971 Patent (i) as an Other Shared Expense to the extent the defense of such 1971 Patent involved a Shared Product in the Profit Share Territory and included in the calculation of Net Profits and Net Losses in accordance with the Sharing Percentages pursuant to Section 11.13.1 and (ii) Licensee may deduct [***] of the remaining costs, expenses, liabilities, damages, recoveries, or settlement payments paid by Licensee pursuant to this Section 12.10.2 from the subsequent payments due from Licensee to Relay in accordance with Section 11.5.1, 11.5.2, 11.5.4, 11.5.5, 11.6.1 or 11.6.2 in accordance with Section 11.6.4(g).

(b) If Licensee notifies Relay that Licensee declines to defend and control the defense of any such action with respect to any Relay Patent or Joint Collaboration Patent under Section 12.10.2 or fails to commence defending any such action Section (a) within [***] following delivery of notice pursuant to Section 12.10.1, Relay will thereupon have the right (but not the obligation) to assume control of such defense, at its own cost and expense (which may include settlement), by counsel of its choice after prior written notice to Licensee.

(c) During the Term of this Agreement, Relay will have the first right (but not the obligation) to defend and control the defense of the validity and enforceability of any Relay Combination Patent. With respect to any such action involving the validity or enforceability of any such Relay Combination Patent, if Relay finds it necessary or desirable for Licensee to join Relay as a party to any such action, Licensee will, at Relay's request and expense, join Relay as a party to such suit and participate with its own counsel at its own cost and expense; provided that Licensee will pay for counsel of its choosing if Licensee chooses not to participate with Relay's counsel; provided further that Relay will retain control of the defense in such claim, suit, or proceeding.

(d) If Relay notifies Licensee that Relay declines to defend and control the defense of any such action with respect to any Generic Relay Combination Patent under Section 12.10.2(c) within [***] following delivery of notice pursuant to Section 12.10.1, Licensee will thereupon have the right (but not the obligation) to assume control of such defense, at its own cost and expense (which may include settlement), by counsel of its choice after prior written notice to Licensee.

12.10.3 Cooperation. Each Party will assist and cooperate with the other Party as such other Party may reasonably request from time to time in connection with its activities set forth in this Section 12.10, including by being joined as a party plaintiff in such action or proceeding, as applicable, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours. In connection with any such defense or claim or counterclaim, the controlling Party will consider in good faith any comments from the other Party and will keep the other Party reasonably informed of any material developments, and will provide copies of all documents filed, in connection with such defense, claim, or counterclaim. During the Term of this Agreement, in connection with the activities set forth in this Section 12.10, each Party will consult with the other as to the strategy for the defense of any Relay Patent or Joint

Collaboration Patent, as applicable; provided that Licensee will have no such consultation right with respect to Relay Combination Patents that are not Generic Relay Combination Patents.

12.11 Defense of Claims Brought by Third Parties

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12.11.1 Notice. If a Party becomes aware of any actual or potential claim that the Development, Manufacture or Commercialization of any Licensed Candidate or Licensed Product (including any Licensee Combination or Relay Pipeline Combination) under this Agreement infringes the intellectual property rights of any Third Party (a "**Third Party Action**"), such Party will promptly notify the other Party.

12.11.2 Defense. If a Third Party Action is commenced against either Party, its Affiliates or its Sublicensees then the Party (or its Affiliate or Sublicensee, as applicable) who is named as the defendant shall have the right (but not the obligation) to defend such Third Party Action at its own expense using counsel of its choice. Notwithstanding the foregoing, if a Third Party Action is commenced against both Relay (or any of its Affiliates or Sublicensees), on the one hand, and Licensee (or any of its Affiliates or Sublicensees), on the other hand (a "**Joint Third Party Action**"), then Licensee will have the right (but not the obligation) to conduct and control defense of the Joint Third Party Action and to compromise or settle the same. Subject to Licensee's right to conduct and control such defense, Relay will be entitled to be represented by independent counsel of its choice at its own expense. If Licensee declines or fails to assert its intention to conduct and control the defense of such Joint Third Party Action within [***] following receipt of notice under Section 12.11.1, then Relay (or its Affiliates or Sublicensees) will have the right (but not the obligation) to defend itself in such Third Party Action with counsel of its choice. The Parties will reasonably cooperate with each other in all Third Party Actions.

12.11.3 Costs of a Third Party Action. Subject to the remainder of this Section 12.11.3, the controlling Party will pay all costs and expenses of defending such Third Party Actions and all liabilities, damages, recoveries or settlement payments associated with such Third Party Action (other than, in the case of a Joint Third Party Action controlled by Licensee as provided in Section 12.11.2, the costs and expenses of Relay if Relay elects to be represented by independent counsel of its choice in such Joint Third Party Action). Notwithstanding the foregoing, with respect to a Third Party Action that alleges the manufacture, use or sale of the Lead Candidate or a Lead Product (including any Licensee Combination or Relay Pipeline Combination including the Lead Candidate or a Lead Product) infringes a Patent Controlled by such Third Party (a "**Third Party Lead Product Action**"), (a) to the extent the Third Party Lead Product Action involves a Shared Product in the Profit Share Territory, then the controlling Party's costs and expenses and liabilities, damages, recoveries or settlement payments for such Third Party Lead Product Action will be deemed to be Other Shared Expenses and included in the calculation of Net Profits and Net Losses in accordance with the Sharing Percentages pursuant to Section 11.3.1; and (b) Licensee may deduct [***] of the remaining costs and expenses and liabilities, damages, recoveries or settlement payments paid by Licensee under this Section 12.11.3 from any subsequent payments due from Licensee to Relay in accordance with Section 11.5.1, 11.5.2, 11.5.4, 11.5.5, 11.6.1 or 11.6.2 in accordance with Section 11.6.4(g). In addition, with respect to a Third Party Action that alleges the Research, Development, Manufacture or Commercialization of a Licensed Candidate or Licensed Product (including any Licensee Combination or Relay Pipeline Combination including a Licensed Candidate or Licensed Product), infringes Prior Agreement Third Party IP,

Relay shall be solely responsible for the costs and expenses and any liabilities, damages, recoveries or settlement payments for such Third Party Action and will promptly reimburse Licensee for any of the foregoing incurred by Licensee.

12.11.4 No Settlement Without Consent. Neither Party will settle or otherwise compromise any Third Party Action by admitting that any Patent within the Relay Patents or Joint Collaboration Patents is invalid or unenforceable without the other Party's prior written consent; provided that Relay may make such admissions with respect to Relay Combination Patents that are not Generic Relay Combination Patents. Without limiting the foregoing, in the event that Relay is the controlling Party, Relay may not, without the prior written consent of Licensee, (a) settle or otherwise compromise a Third Party Action which would require the grant of any license, covenant or other rights to any Third Party that would conflict with or reduce the scope of the rights or licenses granted to Licensee under this Agreement or otherwise adversely affect the interest of Licensee in any respect and (b) enter into any license with such Third Party in connection with any such settlement unless any license or rights granted to Relay are fully sublicensable to Licensee in accordance with the terms of this Agreement.

12.12 Common Interest Disclosures. The Parties have a common legal interest in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the activities under this Agreement or Licensed Candidates or Licensed Products, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the conduct of the activities under this Agreement or Licensed Candidates or Licensed Products. Accordingly, any information or opinions disclosed pursuant to this Agreement by one Party to each other regarding intellectual property or technology owned by Third Parties will be used solely for purposes of the Parties' common legal interests with respect to the conduct of this Agreement. All information and materials will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party. Notwithstanding the foregoing, neither Party's attorney represents the other Party.

12.13 Patent Term Extension

. Relay will reasonably cooperate with Licensee, upon Licensee's reasonable request, in obtaining at Licensee's expense patent term extension or supplemental protection certificates and the like with respect to any Patents within the Relay Patents or Joint Collaboration Patents that claim a Licensed Product, in each country and region where it is possible to do so. Licensee will make the election in accordance with the preceding sentence and Relay agrees to abide by such election; provided that in no event may Licensee make any such election with respect to a Relay Combination Patent that is not a Generic Relay Combination Patent.

ARTICLE 13.
CONFIDENTIALITY

13.1 Nondisclosure

. Except to the extent expressly authorized by this Agreement or otherwise agreed by the Parties in writing, each Party agrees that a Party (the "**Receiving Party**") receiving Confidential Information of the other Party (the "**Disclosing Party**") will (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own proprietary or confidential information of similar kind and nature, but in no event less than a reasonable degree of care, (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted pursuant to this Article 13, and (c) not use, directly or indirectly, such Confidential Information for any purpose except to exercise its rights or perform its obligations as permitted by this Agreement (it being understood that this clause (c) will not create or imply any rights or licenses to a Party that are not expressly granted under this Agreement). The obligations of confidentiality, non-disclosure and non-use under this Section 13.1 will be in full force and effect during the Term and for a period of [***] thereafter. The Receiving Party will, at the Receiving Party's election, return all copies of or destroy (and certify such destruction in writing) the Confidential Information of the Disclosing Party disclosed or transferred to it by the other Party pursuant to this Agreement, within [***] of the termination of this Agreement; provided, however, that a Party may retain one (1) copy of all other Confidential Information in archives solely for the purpose of establishing the contents thereof; provided, further, that such retained copy will remain subject to the terms of confidentiality and non-use set forth herein. Further, upon the termination of this Agreement, the Development Know-How and Materials, the Manufacturing Know-How and Materials, the Relay Phase Ia Trial Data and the Regulatory Materials, in each case as transferred to Licensee hereunder, shall be the Confidential Information of Relay only and without regard to Section 13.2(a).

13.2 Exceptions

. The obligations in Section 13.1 will not apply with respect to any portion of the Confidential Information of the Disclosing Party that the Receiving Party can show by competent written proof:

(a) was known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party;

(b) is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and without any obligation to keep it confidential or any restriction on its use;

(c) is published by a Third Party or otherwise becomes publicly available or enters the public domain, either before or after it is disclosed to the Receiving Party, without any breach by the Receiving Party or its Affiliates of its obligations hereunder;

(d) is published by a Party in accordance with Section 13.6 without any breach by such Party of its obligations hereunder; or

(e) is independently developed by or for the Receiving Party or its Affiliates without reference to, use of or reliance upon the Disclosing Party's Confidential Information.

The exceptions set forth in the foregoing clauses (a) and (e) will not apply to Joint Collaboration IP.

Any combination of features or disclosures will not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party. In addition, Confidential Information will not be deemed to be within the exceptions set forth above merely because such information is embraced by more general information in the public domain or in the possession of the Receiving Party.

13.3 Authorized Disclosure

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13.3.1 Disclosure. Notwithstanding Section 13.1, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party in the following instances:

(a) subject to Section 13.5, to comply with Applicable Law (including the rules and regulations of the U.S. Securities and Exchange Commission or any national securities exchange, any other similar regulatory agencies in a country other than the United States or of any stock exchange or other securities trading institution (for purposes of this Section 13.3.1(a), each an "**Exchange**") or any tax authority), if such disclosure is necessary for such compliance or for such judicial process (including prosecution or defense of litigation);

(b) to a Governmental Authority or Regulatory Authority, provided that reasonable steps are taken to ensure confidential treatment of such Confidential Information (if available);

(c) to prosecute or defend litigation as contemplated by this Agreement;

(d) to any licensor under any Third Party agreement under which a Party receives a (sub)license, to the extent required provided that each such licensor is bound by written confidentiality obligations no less restrictive than those set forth in this Article 13;

(e) to any (i) of its officers, directors, employees, agents or Affiliates solely on a "need to know basis" in the course of conducting activities in accordance with this Agreement in order to carry out its responsibilities or exercise its rights under this Agreement or (ii) bona fide actual or prospective acquirers, underwriters, investors, lenders or other financing sources or permitted Third Party Subcontractors, licensees or Sublicensees, and to employees, officers, directors, agents, consultants and advisers of any such Third Party set forth in clause (ii), in each case on a "need to know basis", provided that each such disclosee set forth in (i) or (ii) is bound by written confidentiality obligations and non-use obligations no less restrictive than those set forth in this Article 13 (with a duration of confidentiality and non-use obligations as is customary in such agreements); provided that with respect to disclosures by a Party to a potential licensee or Sublicensee pursuant to the foregoing clause (ii), such Party (A) will require that all

such disclosure by such Party of the other Party's Confidential Information containing chemical structures, CMC information, patent prosecution matters, financial information, clinical trial strategy or design, or assay protocols prior to execution of a definitive license or sublicense agreement with such licensee or Sublicensee be made only to Third Party subject matter experts who may advise such potential licensee or Sublicensee and (B) may only disclose the structure of the Lead Candidate following execution of a definitive agreement with such licensee or Sublicensee; or

(f) disclosure, solely on a "need to know basis" to its advisors (including attorneys and accountants); provided that, prior to any such disclosure, each disclosee must be bound by written obligations of confidentiality, non-disclosure and non-use no less restrictive than the obligations set forth in this Article 13 (provided, however, that in the case of legal advisors, no written agreement will be required), which for the avoidance of doubt, will not permit use of such Confidential Information for any purpose except those permitted by this Agreement (with a duration of confidentiality and non-use obligations as is customary in such agreements).

13.3.2 Terms of Disclosure. If and whenever any Confidential Information is disclosed in accordance with this Section 13.3, such disclosure will not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). Where reasonably possible and subject to Section 13.5, the Receiving Party will notify the Disclosing Party of the Receiving Party's intent to make any disclosures pursuant to Section 13.3.1(a) sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information, and the Receiving Party will provide reasonable assistance to the Disclosing Party with respect thereto; provided that, in such event, the Receiving Party will use reasonable measures to ensure confidential treatment of such information and will only disclose such Confidential Information of the Disclosing Party as is necessary for the purposes of Section 13.3.1(a), as applicable; provided, further, that if either Party concludes that a copy of this Agreement must be filed with an Exchange, then such Party will seek confidential treatment for portions of this Agreement from such Exchange will, a reasonable time prior to any such filing, provide the other Party with a copy of such Agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, will provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions within [***], and will take such Party's reasonable comments into consideration before filing such agreement and use Commercially Reasonable Efforts to have terms identified by such other Party afforded confidential treatment by the applicable Exchange and shall thereafter provide reasonable advance notice ([***]) and opportunity for comment on any subsequent changes to such filing including opportunity to participate in any meetings with the Exchange related thereto; provided, further, that notwithstanding the foregoing, no such notice will be required for any disclosure made in connection with any submission by either Party or any of its Affiliates to any tax authority. In filing the Agreement with an Exchange Relay shall, whether or not requested by Licensee, (i) redact all Exhibits and any references to scientific Confidential Information of Licensee, and (ii) with respect to any financial terms, to the extent not allowed to redact, request confidential treatment for such financial terms, including the basis for the royalties under Section 11.10.

13.4 Terms of this Agreement

. The Parties agree that this Agreement and all of the respective terms hereof will be deemed to be Confidential Information of both Relay and Licensee with each Party treated as the Receiving Party, and each Party agrees not to disclose any of them without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed, except that each Party may disclose any of them in accordance with the provisions of Section 13.3.1(a), 13.3.1(c), 13.3.1(e)(i), 13.3.1(f), 13.3.2 and 13.5.1.

13.5 Publicity

. Notwithstanding Section 13.3

13.5.1 The Parties will jointly issue a press release, in the form attached hereto as Schedule 13.5, regarding the signing of this Agreement on a date to be determined by the Parties following the Effective Date.

13.5.2 Except as set forth herein, Relay may not make any press release or public announcements regarding this Agreement or any matter covered by this Agreement, including the Development, Manufacture or Commercialization of Licensed Candidates or Licensed Products, without the prior written consent of Licensee. Except as set forth herein, Licensee may not make any press release or public announcements regarding this Agreement or the Development of Shared Products during the Opt-In Term or the Commercialization of Relay Pipeline Combinations without the prior written consent of Relay. In the event that a Party (the "**Publishing Party**") reasonably believes it is required to issue a press release or make another public announcement to comply with Applicable Law, the Publishing Party may only issue such press release or other public announcement if the Publishing Party provides the text of such planned disclosure to the other Party (the "**Non-Publishing Party**") in no less than [***] prior to disclosure, and incorporates all reasonable comments of the regarding such disclosure.

13.5.3 For the avoidance of doubt, this Section 13.5 does not apply to press releases and public announcements by [***].

13.6 Publications

.Notwithstanding the other provisions of this Article 13, both Parties recognize that the publication or disclosure of papers, presentations, abstracts or any other written or oral presentations regarding results of and other information regarding the Development, Manufacture or Commercialization activities under this Agreement may be beneficial to both Parties, and the Parties agree that the JDT will develop a publication strategy in accordance with Section 10.2.2(d) in pursuance thereof; provided that such publications or presentations are subject to reasonable controls to protect Confidential Information, the patentability of inventions and other commercial considerations. Accordingly, except for disclosures permitted in accordance with the other provisions of this Article 13, the following shall apply with respect to papers, posters, publications, presentations and any other public disclosures regarding the Development, Manufacture or Commercialization activities under this Agreement proposed for disclosure by either Party (each, and collectively, as used in this Section 13.6 "**Publications**"):

13.6.1 With respect to any Publications proposed for disclosure by Licensee, except as provided in Section 13.6.2, Licensee shall be free to make, publish and disclose such Publications at its discretion. With respect to any such Publication that discloses Licensee's use of the Licensed Candidates or Licensed Products, including the results of any Clinical Trials with respect thereto, Licensee shall (i) acknowledge Relay in such Publication and (ii) provide a courtesy copy of the draft Publication prior to its public disclosure.

13.6.2 With respect to any Publication proposed for disclosure by Licensee which (a) includes Confidential Information of Relay other than the Development Know-How and Materials, the Manufacturing Know-How and Materials, the Relay Phase Ia Trial Data and the Regulatory Materials transferred to Licensee hereunder, (b) that relates to a Relay Pipeline Combination or (c) that is proposed prior to launch of a Shared Product during the Opt-In Term and relates to such Shared Product, Licensee will deliver to Relay a copy of the proposed Publication at least [***] prior to submission for publication or presentation. Relay shall review such submitted materials and respond to Licensee as soon as reasonably practicable, but in any case within [***] of receipt thereof. Relay will have the right to (i) propose modifications to the publication or presentation for patent reasons or trade secret reasons or to remove Confidential Information of the Relay or its Affiliates or Sublicensees, and Licensee will remove all Confidential Information of Relay or its Affiliates or Sublicensees if requested by Relay and otherwise use good faith efforts to reflect Relay's reasonable comments, or (ii) request a reasonable delay in publication or presentation in order to protect patentable information. If Relay requests a delay to enable Relay to file patent applications protecting Relay's right in such information, then Licensee will delay such submission or presentation for a period of [***] (or such shorter period as may be mutually agreed by the Parties).

13.6.3 With respect to any Publication proposed for disclosure by Relay (or its Affiliates or Sublicensees or Third Party Subcontractors or any other Third Party under Existing Third Party Agreements or future agreements as permitted in accordance with Section 9.1.3, including any investigators or academic or non-profit collaborators) which (a) includes Confidential Information of Licensee or (b) relates to a Licensed Candidate or Licensed Product (including any Relay Phase Ia Trial Data), Relay will deliver to Licensee a copy of the proposed Publication at least [***] prior to submission for publication or presentation. Licensee shall review such submitted materials and respond to Licensee as soon as reasonably practicable, but in any case within [***] of receipt thereof. Licensee will have the right to (i) propose modifications to the publication or presentation for patent reasons or trade secret reasons or to remove Confidential Information of the Licensee or its Affiliates or Sublicensees, and Relay will remove all Confidential Information of Licensee if requested by Licensee and otherwise use good faith efforts to reflect Licensee's reasonable comments, or (ii) request a reasonable delay in publication or presentation in order to protect patentable information. If Licensee requests a delay to enable Licensee to file patent applications protecting Licensee 's right in such information, then Relay will delay such submission or presentation for a period of [***].

13.6.4 Notwithstanding the foregoing in Section 13.6.3 above, (a) with respect to any Publication that relates to the Relay Phase Ia Trial Data or any other data (clinical and pre-clinical) regarding a Licensed Candidate or Licensed Product, but not for any proposed Publication that relates solely to a Relay Pipeline Combination, in the event that Licensee in its reasonable and good faith belief determines that any foregoing Publication may negatively impact the Development or Commercialization of any Licensed Candidate or Licensed Product, Licensee shall notify Relay of such belief and the Parties shall discuss and negotiate in good faith for an alternative solution, and Relay acknowledges and agrees that Licensee may require Relay to delay the disclosure of any such Publication or may require Relay not to publish such Publication indefinitely and (b) with respect to any Publication that discloses Relay's use of the Licensed Candidates or Licensed Products only in a Relay Pipeline Combination that is not subject to the

foregoing subclause (a), Relay shall provide a courtesy copy of the draft Publication prior to its public disclosure.

13.6.5 With respect to any proposed Publications by investigators or academic or non-profit collaborators or any other Third Party in accordance with Section 13.6.3 above, such materials will be subject to review under this Section 13.6, and as between the Parties, it shall be Relay's sole responsibility to ensure its compliance under this Agreement, as well as its compliance under any other agreement it entered into with any Third Party.

13.7 Use of Names

. Except as expressly provided herein, neither Party will mention or otherwise use the name, logo, or Trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 13.7 will not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law.

13.8 Safeguards. If Relay is conducting Development activities for a Relay Pipeline Combination, and Licensee is conducting Development activities for a [***] Combination that includes a compound or product that is Directed to the same target as the Relay Pipeline Compound included in such Relay Pipeline Combination ([***]) (such Licensee Combination Development activities and such Relay Pipeline Combination Development activities, a "**Competing Program**" of the Party conducting such activities), then each Party will establish reasonable protections and safeguards to protect against the other Party's Confidential Information regarding such other Party's Confidential Information of the Competing Program [***].

ARTICLE 14.
REPRESENTATIONS AND WARRANTIES

14.1 Representations and Warranties of Both Parties

. Each Party hereby represents and warrants to the other Party, as of the Effective Date, that:

(a) such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation and has full corporate power and authority to enter into this Agreement, and to carry out the provisions hereof;

(b) such Party has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

(c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with its terms, except to the extent that enforcement of the rights and remedies created hereby is subject to (i) bankruptcy, insolvency, reorganization, moratorium and other similar laws of general application affecting the rights and remedies of creditors, or (ii) laws governing specific performance, injunctive relief and other equitable remedies;

(d) the execution, delivery and performance of this Agreement by such Party does not conflict with any agreement or any provision thereof, or any instrument or

understanding, oral or written, to which it is a party or by which it is bound, nor violate any Applicable Law of any Governmental Authority having jurisdiction over such Party;

(e) no government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Law currently in effect, is or will be necessary for the consummation of the transactions contemplated by this Agreement or for the performance by it of its obligations under this Agreement (including, in the case of Relay, the grant of the rights to Licensee hereunder), except for any filing required under Antitrust Laws;

(f) that no consideration received by such Party under this Agreement is intended by such Party to be a prohibited payment for the recommending or arranging for the referral of business or ordering of products or services, nor is any such consideration intended by such Party to induce illegal referrals of business under Applicable Law; and

(g) it has obtained all necessary authorizations, consents and approvals of any other Person that is required to be obtained by it as of the Effective Date in connection with, the transaction contemplated by this Agreement (including, in the case of Relay, the grant of the rights to Licensee hereunder).

14.2 Representations and Warranties of Relay

. Relay hereby represents and warrants to Licensee, as of the Effective Date, that:

(a) Schedule 14.2(a) contains a complete and accurate list of all Patents Controlled by Relay or its Affiliates that are necessary or reasonably useful to Research, Develop, Manufacture or Commercialize any compound that is Directed to the Collaboration Target. Except for the Patents set forth on Schedule 14.2(a), Relay and its Affiliates do not Control any Patent that is necessary or reasonably useful to Research, Develop, Manufacture or Commercialize any compound that is Directed to the Collaboration Target;

(b) all issued Patents set forth on Schedule 14.2(a) (i) are in full force and effect, (ii) have been Prosecuted and Maintained in good faith, and (iii) exist and, to the Knowledge of Relay, are not invalid or unenforceable, in whole or in part;

(c) all current and former officers, employees, contractors, consultants and sublicensees of Relay who are inventors of or have otherwise contributed in a material manner to the creation or development of any Relay Patents or Relay Know-How have executed and delivered to Relay or such Affiliate an assignment or other agreement regarding the protection of proprietary information and the assignment to Relay of any such Relay Patents or Relay Know-How, and with respect to any such Relay Patents (i) all inventors of such Relay Patents are correctly identified, (ii) they have been timely and duly filed in such a manner as to perfect title and preserve priority entitlement, including by virtue of assignment documents associated with each priority filing, (iii) all filing and renewal fees payable with respect thereto have been timely paid, and (iv), to the Knowledge of Relay, no current officer, employee, agent, or consultant of Relay or any of its Affiliates is in violation of any term of any assignment or other agreement regarding the protection of Patents or other intellectual property or proprietary information of Relay or such Affiliate or of any employment contract or any other contractual obligation relating to the relationship of any such Person with Relay;

(d) except as set forth on Schedule 14.2(d), all Relay Patents that claim the Lead Candidate are exclusively owned by Relay or its Affiliates;

(e) The Relay IND and all Know-How contained or incorporated by reference therein and all Relay Phase Ia Trial Data is exclusively owned by Relay or its Affiliates;

(f) Relay's interest in the Relay Patents and Relay Know-How is free and clear of all liens, claims, security interests or other encumbrances of any kind that would interfere, or the exercise of which would interfere, with Licensee exercising any of the licenses or rights granted to it hereunder;

(g) Schedule 14.2(g) contains a complete and accurate list of all agreements with a Third Party pursuant to which Relay Controls any Relay Patents that claim the Lead Candidate or Relay Know-How that relates to the Lead Candidate Controlled as of the Effective Date and Licensee has been provided with complete and accurate copies of each such agreement (in redacted form to the extent necessary to comply with confidentiality restrictions);

(h) (i) to the Knowledge of Relay, each Existing Third Party Agreement is in full force and effect and is valid and enforceable in accordance with its terms, (ii) no written notice of default or termination has been received or given by Relay under any Existing Third Party Agreement, and (iii) to the Knowledge of Relay, no event has occurred or circumstance exists that (with or without notice or lapse of time) that would give a party the right to declare a default or terminate any Existing Third Party Agreement;

(i) no claim has been issued and served against Relay or any of its Affiliates that alleges that any Relay Patent is invalid or unenforceable;

(j) Except as set forth on Schedule 14.2(j), Relay is not subject to any payment obligations to Third Parties as a result of the execution or performance of this Agreement in order to maintain any rights of Relay with respect to any Relay Patents or Relay Know-How in the Field licensed hereunder or any other Patent or Know-How that would be included as Relay Patents or Relay Know-How in the Field licensed hereunder but for non-compliance with such payment obligations;

(k) Except as set forth on Schedule 14.2(k), Relay has not granted any right or license to any Third Party under the Relay Patents or Relay Know-How for any Licensed Candidate in the Field that would conflict with or limit the scope of any of the rights or licenses granted to Licensee hereunder;

(l) No funding provided by a Governmental Authority was used in activities related to the Research, Development or Manufacture of the Lead Candidate that resulted in any grant to such Governmental Authority of ownership in, or license under, any Relay Patents or any Relay Know-How that is incorporated in any Relay Patents;

(m) Relay and, to the Knowledge of Relay, its former and current employees, consultants, and agents have complied with all Applicable Laws in the development or creation of the Relay Patents and Relay Know-How, including any duties of candor to applicable patent offices, in connection with the filing, Prosecution and Maintenance of the Relay Patents,

including conducting due inquiry to determine the correct inventorship of the inventors listed in the 1971 Patents;

(n) Relay has not received any written notice of any claim that any Patent or Know-How owned or controlled by a Third Party would be infringed or misappropriated by the Research, Development, Manufacture, or Commercialization of any Licensed Candidate or Licensed Product in the Field;

(o) Relay owns all right, title and interest in and to the Lead Candidate;

(p) Except as set forth on Schedule 14.2(p), to the Knowledge of Relay, the Research, Development, Manufacture, and Commercialization of any Licensed Candidate or Licensed Product in the Field as contemplated hereunder does not violate, infringe, misappropriate or otherwise conflict or interfere with any Patent or any potential Patent claim based on disclosures in any Patent or any other intellectual property or proprietary right of any Person;

(q) The [***] ("**DSUR**") that Relay has disclosed to Licensee prior to the Effective Date sets forth a true and complete list of all information in Relay's Control concerning side effects, injury, toxicity or sensitivity reaction and incidents or severity thereof with respect to the Lead Candidate or Phase Ia Product that would be required to be included in a DSUR with respect to the Phase Ia Clinical Trial if a DSUR were to be submitted to the FDA on the Effective Date;

(r) there are no claims, judgments, settlements, litigations, suits, actions, disputes, arbitration, judicial or legal, administrative or other proceedings or governmental investigations pending or, to the Knowledge of Relay, threatened against Relay or any of its Affiliates which would be reasonably expected to adversely affect or restrict the ability of Relay to consummate or perform the transactions contemplated under this Agreement;

(s) Phase Ia Product, including the Inventory transferred to Licensee by Relay pursuant to the Technology Transfer, has been manufactured (including the facilities and equipment used in its manufacture), stored, and handled in material compliance with, and conform to, then-current specifications, cGMPs (if applicable) and other Applicable Laws. Title to Inventory shall pass to Licensee free and clear of any liens or encumbrances. Neither Relay, any of its Affiliates, nor, to the Knowledge of Relay, their respective CMOs has received: (i) any FDA Form 483 Notice of Observation, or similar notice from any Governmental Authority, relating to the Phase Ia Product or the facilities in which the Phase Ia Product are manufactured; (ii) any FDA Notices of Adverse Findings, or similar notice from any Governmental Authority, with respect to the Phase Ia Product; or (iii) any "warning letters," or "untitled letters," or other similar Governmental Authority notice of inspectional observations or deficiencies or other material written correspondence from any other Regulatory Authority concerning the Phase Ia Product or, to the Knowledge of Relay, the facilities in which the Phase Ia Product is manufactured;

(t) the Relay Phase Ia Trial and all other preclinical and clinical studies conducted by Relay and its Affiliates for the Lead Candidate and the Phase Ia Product have been conducted in accordance with all applicable Regulatory Materials and all Applicable Laws, including as applicable GCP, GLP, GMP, "Informed Consent" and "Institutional Review Board"

regulations, patient privacy and security regulations and all applicable requirements relating to the protection of human subjects for its Clinical Trials as required by the FDA or their equivalents in the country in which the clinical study is conducted. Relay and its Affiliates are, and at all times have been, in compliance with all adverse event reporting requirements applicable to the Phase Ia Product. Neither Relay nor any of its Affiliates have received any written notice for any Regulatory Authority relating to any violation of any Regulatory Materials or Applicable Laws in conducting any such preclinical or clinical studies. Neither Relay, any of its Affiliates, nor any of their respective officers or employees or, to the Knowledge of Relay, agents have made an untrue statement of material fact to any Regulatory Authority (whether in a submission to such Regulatory Authority or otherwise) or failed to disclose a material fact required to be disclosed to any Regulatory Authority with respect to the Lead Candidate or the Phase Ia Product; and

(u) neither Relay nor any of its Affiliates has knowingly withheld any material information in its possession from Licensee in response to Licensee's reasonable inquiries in connection with its due diligence relating to Licensed Candidates or Licensed Products, this Agreement and the underlying transaction, and to the Knowledge of Relay, the information that Relay and its Affiliates have provided to Licensee is up-to-date and accurate in all material respects.

14.3 Representations and Warranties of Licensee

. Licensee hereby represents and warrants to Relay, as of the Effective Date:

14.3.1 [***]

14.3.2 there are no claims, judgments, settlements, litigations, suits, actions, disputes, arbitration, judicial or legal, administrative or other proceedings or governmental investigations pending or, to the Knowledge of Licensee, threatened against Licensee or any of its Affiliates which would be reasonably expected to adversely affect or restrict the ability of Licensee to consummate or perform the transactions contemplated under this Agreement.

14.4 Acknowledgement. Licensee hereby acknowledges that the transfer of certain technical data, computer software, laboratory prototypes or other commodities as contemplated under this Agreement (including in connection with the Development, Manufacture or Commercialization of Licensed Candidates or Licensed Products) may be subject to Applicable Laws controlling their export, some of which prohibit or require a license for the export of certain types of technical data, to certain specified countries and that Relay does not represent that a license will not be required in connection with such transfer under this Agreement, nor that if required, it will be issued.

14.5 Disclaimer

. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED (AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES NOT EXPRESSLY PROVIDED IN THIS AGREEMENT), INCLUDING WITH RESPECT TO ANY PATENTS OR KNOW-HOW, OR MATERIALS, INCLUDING WARRANTIES OF VALIDITY OR ENFORCEABILITY OF ANY PATENTS, TITLE, QUALITY, COMPLETENESS, ACCURACY, MERCHANTABILITY, FITNESS FOR A

PARTICULAR USE OR PURPOSE, PERFORMANCE, AND NONINFRINGEMENT OF ANY THIRD PARTY PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, AND EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, EACH PARTY DISCLAIMS ANY WARRANTIES WITH REGARDS TO: (A) THE SUCCESS OF ANY LICENSED CANDIDATES OR LICENSED PRODUCTS; OR (B) THE SAFETY OR USEFULNESS FOR ANY PURPOSE OF THE LICENSED CANDIDATES, OR LICENSED PRODUCTS.

ARTICLE 15.
INDEMNIFICATION; INSURANCE

15.1 General Indemnification by Licensee

. Licensee will indemnify, defend and hold harmless Relay, its Affiliates, and its and their respective directors, officers, employees, agents, [***], Relay Sublicensees, Third Party Subcontractors, successors and assigns, from and against any and all Losses to the extent arising out of or attributable to any Third Party Claim based upon:

(a) any material breach by Licensee of any of its representations, warranties, covenants, agreements or obligations under this Agreement; or

(b) any Research, Development, Manufacturing or Commercialization of a Licensed Candidate or Licensed Product (including as part of [***] Combinations or [***] Other Combinations) by or on behalf of Licensee or any of its Affiliates or any Licensee Sublicensees;

provided, however, in each case ((a) through (b)), that such indemnity will not apply to the extent that (i) Relay has an indemnification obligation pursuant to Section 15.2 for such Losses or (ii) such Losses arise out of the negligence, gross negligence or willful misconduct of Relay or its Affiliates or Relay Sublicensees or its or their respective directors, officers, employees or agents, including any of its Third Party Subcontractors [***], in connection with this Agreement.

15.2 General Indemnification by Relay

. Relay will indemnify, defend and hold harmless Licensee, its Affiliates and its and their respective directors, officers, employees, agents, Licensee Sublicensees, Third Party Subcontractors, successors and assigns, from and against any and all Losses to the extent arising out of or attributable to any Third Party Claim based upon:

(a) any material breach by Relay of any of its representations, warranties, covenants, agreements or obligations under this Agreement; or

(b) any Research, Development, Manufacturing or Commercialization of a Licensed Candidate or Licensed Product (including as part of Relay Pipeline Combinations) by or on behalf of Relay or any of its Affiliates.

provided, however, in each case ((a) through (b)), that such indemnity will not apply to the extent that (i) Licensee has an indemnification obligation pursuant to Section 15.1 for such Losses or (ii) such Losses arise out of the negligence, gross negligence or willful misconduct of Licensee, its Affiliates or Licensee Sublicensees or its or their respective directors, officers, employees or agents, including any of its Third Party Subcontractors, in connection with this Agreement.

15.3 Indemnification Procedure.

15.3.1 Notice of Claim. All indemnification claims in respect of a Party, its Affiliates, or their respective directors, officers, employees, agents, Sublicensees and Third Party Subcontractors will be made solely by such Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party will give the indemnifying Party (the "**Indemnifying Party**") written notice (an "**Indemnification Claim Notice**") of any Losses or learning of the Third Party Claim upon which such Indemnified Party intends to base a request for indemnification under Section 15.1 or Section 15.2, as applicable, promptly after receipt by such Indemnified Party of actual notice of the Third Party Claim. A delay or failure to provide such notice will not affect the indemnification provided under Section 15.1 or Section 15.2, as applicable, except to the extent the Indemnifying Party has been actually prejudiced as a result of such delay or failure. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party will furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

15.3.2 Control of Defense. Subject to Sections 12.10 and 12.11, at its option, the Indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [***] after the Indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the Indemnifying Party will not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor will it constitute a waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party. In the event the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party will immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the Indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 15.3.3, the Indemnifying Party will not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the Indemnifying Party. In the event that it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party will reimburse the Indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the Indemnifying Party in its defense of the Third Party Claim.

15.3.3 Right to Participate in Defense. Without limiting Section 15.3.2, any Indemnified Party will be entitled to participate in, but not control (unless the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 15.3.2), the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment will be at the Indemnified Party's own cost and expense unless (a) the employment thereof has been specifically authorized by the Indemnifying Party in writing, (b) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 15.3.2 (in which case the Indemnified Party will control the defense), or (c) the interests of the indemnitee and the Indemnifying Party with respect to such Third Party Claim are

sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles.

15.3.4 Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim that are subject to indemnification by the Indemnifying Party under this Article 15, and (a) that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, (b) which includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim and (c) as to which the Indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the Indemnifying Party will have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, will deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 15.3.2, the Indemnifying Party will have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; provided that it obtains the prior written consent of the Indemnified Party (which consent will not be unreasonably withheld or delayed). If the Indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim; provided that the Indemnified Party will not settle any Third Party Claim without the prior written consent of the Indemnifying Party, not to be unreasonably withheld or delayed.

15.3.5 Cooperation. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party will, and will cause each indemnitee to, reasonably cooperate in the defense or prosecution thereof and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation will include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making the Indemnified Party and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder; provided, however, that the Indemnified Party will be given the opportunity to redact any Confidential Information not relevant to the Third Party Claim; provided, further, that the Indemnifying Party will keep confidential any Confidential Information disclosed or made available during such visits. The Indemnifying Party will reimburse the Indemnified Party for all its reasonable Out-of-Pocket Costs in connection therewith.

15.4 Insurance

15.4.1 . During the Term and for a period of [***] after the expiration or termination of this Agreement (provided that the time periods set forth in Section 15.4.1(a) or 15.4.1(b) will control in the event of a conflict with the foregoing), each Party will have and maintain in full force and effect, at its own expense, insurance coverage to include: [***].

15.4.2 All insurance maintained pursuant to this Section 15.4 will be underwritten by companies with an AM best rating of at least A-VII. Each Party will provide the other Party with written evidence of such insurance upon request. Each Party will provide the other Party written notice at least [***] prior to the cancellation, non-renewal or material change in such

insurance. Each Party shall name the other Party as additional insured under its commercial general liability and products liability insurance policies.

15.4.3 Notwithstanding the foregoing, Licensee may satisfy the insurance requirements of this Section 15.4 through a program of self-insurance. The minimum amounts of insurance coverage required under this Section 15.4 will not be construed to create a limit of liability with respect to indemnification under Section 15.1.

15.5 LIMITATION OF LIABILITY

. EXCEPT IN THE EVENT OF (A) A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 9, (B) A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, (C) A BREACH BY A PARTY OF ITS OBLIGATIONS UNDER ARTICLE 12 OR ARTICLE 13, OR (D) ANY DAMAGES REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 15, NEITHER RELAY NOR LICENSEE, NOR ANY OF THEIR RESPECTIVE AFFILIATES, WILL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES UNDER OR IN CONNECTION WITH THIS AGREEMENT FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS OR LOST REVENUES), WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), CONTRIBUTION OR OTHERWISE, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE.

ARTICLE 16.
TERM AND TERMINATION

16.1 Term

. Except as set forth in Article 17, this Agreement will become effective on the Effective Date and, unless earlier terminated in accordance with this Article 16, will remain in effect (a) on a Licensed Product-by-Licensed Product and country-by-country basis until the expiration of the Royalty Term for such Licensed Product in such country; provided that the term of this Agreement for any Shared Product will expire on the date on which Licensee is no longer Commercializing such Shared Product in the Profit Share Territory and (b) for any [***] until the expiration of the [***] (the "**Term**"). Following expiration of the Royalty Term for any Licensed Product in a given country or the [***], no further royalties will be payable in respect of sales of such Licensed Product in such country or the [***], as applicable, and, thereafter the license granted to Licensee under Section 12.1.1 with respect to such Licensed Product in such country will automatically become fully paid-up, perpetual, irrevocable and royalty-free. Upon expiration of the Royalty Term for all Licensed Products in all countries in the Territory (or the Royalty Territory if Opt-In Term is continuing), all licenses granted to Licensee under Section 12.1.1 will automatically become fully paid-up, perpetual, irrevocable and royalty-free in the Territory or the Royalty Territory, as applicable.

16.2 Termination for Convenience

. At any time during the Term, Licensee may terminate this Agreement in its entirety immediately following [***] written notice to Relay.

16.3 Termination for Breach

. This Agreement may be terminated by either Party for the material breach by the other Party of its obligations under this Agreement; provided that the breaching Party has not cured such breach within [***] after the date of written notice to the

breaching Party of such breach (the "**Cure Period**"), which notice will describe such breach in reasonable detail and will state the non-breaching Party's intention to terminate this Agreement pursuant to this Section 16.3; provided, however, if such breach is not capable of being cured within such Cure Period, the Cure Period shall be extended for such amount of time that the Parties agree to in writing is reasonably necessary to cure such breach, so long as the breaching Party is using diligent efforts to do so; provided further than in all cases in which the breach is a failure to pay any amount due hereunder, the Cure Period will be limited [***]. Any such termination of this Agreement under this Section 16.3 will become effective at the end of the Cure Period, unless the breaching Party has cured such material breach prior to the expiration of such Cure Period. Any Dispute as to whether a notice of termination pursuant to this Section 16.3 is proper, or whether a breach has occurred, is material or has been cured, shall be resolved under Section 18.9. In such event, if the allegedly breaching Party is found to be in material breach, the remaining Cure Period (meaning, any portion of the Cure Period that did not elapse between the notice of breach and the notification of a Dispute with respect thereto) will be counted from the date of resolution of such Dispute. If Relay has the right to terminate this Agreement due to a material breach by Licensee, and if such breach relates solely to a given Lead Candidate or Lead Product or solely to a Back-Up Compound or Back-Up Product, then Relay may only terminate this Agreement with respect to all Lead Candidates and Lead Products or all Back-Up Compounds and Back-Up Products, respectively. In the event a Sublicensee or Third Party Subcontractor of a Party breaches its sublicense agreement or subcontractor agreement with such Party, as applicable, such that the sublicensing or subcontracting Party would be in breach of this Agreement, and such Sublicensee or Third Party Subcontractor is unable or unwilling to cure such breach, then without limiting any other right of the non-breaching Party to pursue any and all remedies against the sublicensing or subcontracting Party or its Sublicensee or Third Party Subcontractor, the non-breaching Party may not exercise its right to terminate this Agreement pursuant to this Section 16.3 if the sublicensing or subcontracting Party terminates the applicable sublicense agreement or subcontracting agreement with the breaching Sublicensee or Third Party Subcontractor.

16.4 Termination for Bankruptcy

. If either Party makes a general assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not dismissed, discharged, bonded or stayed within [***] after the filing thereof, the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party; provided that, in connection therewith, the provisions of Section 12.5 will apply.

16.5 Termination for Patent Challenge. Relay may terminate this Agreement upon written notice to Licensee if Licensee or any of its Affiliates or any Licensee Sublicensee directly or indirectly challenges in a legal or administrative proceeding the patentability, enforceability or validity of any Patent within the Relay Patents (each, a "**Patent Challenge**"); provided, however, that Relay shall first notify Licensee in writing that it believes Licensee or any of its Affiliates or any Licensee Sublicensee has initiated a Patent Challenge and shall give Licensee no less than [***] to withdraw, or have its Affiliate or Licensee Sublicensee withdraw, such Patent Challenge (or in the case of a Licensee Sublicensee, for Licensee to terminate the applicable sublicense of such Licensee Sublicensee if such Licensee Sublicensee is unwilling to withdraw the Patent Challenge). In any event, (a) this Section 16.5 will not apply to any such Patent Challenge that is first made by Licensee or any of its Affiliates or Licensee Sublicensees in defense of a claim of patent infringement brought by Relay, (b) with respect to any Third Party that becomes an Affiliate

of Licensee during the Term as a result of a Change of Control of Licensee or acquisition of such Third Party by Licensee, this Section 16.5 will not apply to any Patent Challenge involving such Third Party if such Patent Challenge was initiated before the signing of the definitive document(s) whereby such Third Party becomes such an Affiliate and such Third Party promptly terminates the Patent Challenge within [***] after the closing of the applicable Change of Control.

16.6 Termination for Cessation. Relay may, at its election, terminate this Agreement upon [***] prior written notice to Licensee in the event that Licensee, its Affiliates and Licensee Sublicensees have not conducted any Research, Development, Manufacturing or Commercialization activities with respect to any Licensed Candidate or Licensed Product for a continuous period of [***]; provided that (a) if such cessation is a result of a Third Party Action, safety concern, force majeure, injunction or other operation of law, any action by any Regulatory Authority that prevents, limits or otherwise adversely affects any such Research, Development, or Commercialization activity, including for safety or Manufacturing issues, or any material breach by Relay or any of its Affiliates of its obligations under this Agreement or under the SAE Management Plan, the Quality Agreement, the Pharmacovigilance Agreement, the Supply Agreement or any Coordinated Promotion Agreement, such [***] period will be extended for each day any of the foregoing listed in this clause (a) caused such cessation and (b) if such cessation of activity is due to a Manufacturing issue other than as described in clause (a) and Licensee is using Commercially Reasonable Efforts to seek to remedy such issue, such [***] period will be extended for a reasonable period of time as is reasonably necessary to resolve the Manufacturing issue.

16.7 Termination for Failure to Obtain Merger Control

. Each of Relay and Licensee will have the right to terminate this Agreement on a country-by-country basis (with respect to any affected country), effective immediately upon written notice to the other Party, in the event that (a) a Governmental Authority obtains a preliminary injunction under any applicable Antitrust Law to enjoin the transactions contemplated by this Agreement or (b) the Parties have not secured the clearance, approval, expiration, or termination of all applicable merger control waiting periods under applicable Antitrust Law on or prior to [***] after the effective date of all applicable Merger Control Filings in such country.

16.8 Effects of Termination

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16.8.1 Generally. Upon termination of this Agreement in its entirety pursuant to this Article 16:

(a) the Parties' rights, licenses and obligations under this Agreement will terminate and neither Party will have any further rights or obligations under this Agreement from and after the effective date of termination ("**Termination Date**"), except as set forth in this Section 16.8 or Section 16.11;

(b) Licensee and its Affiliates and Sublicensees may complete and sell any work-in-progress, committed supply or inventory of the applicable Licensed Products that exist as of the Termination Date, provided that Licensee pays Relay the applicable royalty or other amounts due on such sales of Licensed Products in accordance with the terms and conditions of this Agreement;

(c) any Compulsory Sublicense shall remain in full force and effect to the extent required by Applicable Law, and

(d) any existing, permitted sublicense granted by Licensee to a Licensee Sublicensee hereunder (and any further sublicenses thereunder) shall, upon the written request of Licensee, remain in full force and effect, provided that (i) such Licensee Sublicensee is not then in breach of its sublicense agreement (and, in the case of termination by Relay for breach by Licensee pursuant to Section 16.3, that such Licensee Sublicensee and any further Sublicensees did not cause the breach that gave rise to the termination by Relay); and (ii) and such Licensee Sublicensee agrees to be bound to Relay under the terms and conditions of such sublicense agreement.

16.8.2 Termination by Relay Pursuant to Section 16.3, Section 16.4, Section 16.5, Section 16.5 or Termination by Licensee Pursuant to Section 16.2. In the event of termination of this Agreement by Relay pursuant to Section 16.3, Section 16.4, Section 16.5 or Section 16.5 or by Licensee pursuant to Section 16.2, in each case, effective upon the Termination Date:

(a) except as set forth in Section 16.11, all rights and licenses granted by Relay to Licensee herein with respect to the Licensed Candidates, Licensed Products and Relay IP will terminate;

(b) if Licensee or any of its Affiliates or Licensee Sublicensees have any ongoing Development or Commercialization activities at termination or expiration of this Agreement with respect to a Relay Pipeline Combination Eligible Licensed Product and at such time Relay or any of its Affiliates or any Relay Sublicensee has ongoing Development or Commercialization activities with respect to the Combination Use of such Relay Pipeline Combination Eligible Licensed Product in a Relay Pipeline Combination (such Relay Pipeline Combination Eligible Licensed Product a "**Terminated Relay Pipeline Combination Eligible Licensed Product**"), then Relay may notify Licensee in writing that it (through itself, an Affiliate or a Relay Sublicensee) wishes to continue Development or Commercialization activities with respect to such Terminated Relay Pipeline Combination Eligible Licensed Product. If Relay delivers such notice to Licensee within [***] after the Termination Date, then Licensee and Relay shall meet and negotiate in good faith the appropriate license, financial and other terms and conditions for Relay to receive (i) a transition of ongoing Development or Commercialization activities with respect to such Terminated Relay Pipeline Combination Eligible Licensed Product to Relay, which transition may include a transfer of Regulatory Materials, assignment of clinical trial agreements, transfer of biological materials, transitional distributor or supply arrangement, or a transfer or assignment of certain trademarks, as applicable, or (ii) a non-exclusive, sublicensable (through multiple tiers, subject to the provisions of Section 12.2 (mutatis mutandis)), non-transferable (except as set forth in Section 18.3 (mutatis mutandis)), worldwide, royalty-bearing license under Licensee IP and other Patents or Know-How Controlled by Licensee and then used by or on behalf of Licensee or its Affiliate in connection with the Development or Commercialization of a Terminated Relay Pipeline Combination Eligible Licensed Product, in each case, to Research, Develop, Manufacture or Commercialize the Terminated Relay Pipeline Combination Eligible Licensed Product solely for Combination Use in the applicable Relay Pipeline Combination (including any improvements, modifications, or enhancements to any such product or combination) (the license, financial and other terms and conditions described in this

sentence, the "**Terminated Relay Pipeline Combination Eligible Licensed Product Terms**"); and

(c) if Licensee or any of its Affiliates or Licensee Sublicensees have any ongoing Development or Commercialization activities at termination or expiration of this Agreement with respect to a Licensed Candidate or Licensed Product other than a Terminated Relay Pipeline Combination Eligible Licensed Product (such Licensed Candidate or Licensed Product, a "**Terminated Other Licensed Product**"), then Relay may notify Licensee in writing that it (through itself, an Affiliate or a Relay Sublicensee) wishes to continue Development or Commercialization with respect to such Licensed Candidate or Licensed Product and to receive a transition of ongoing Development or Commercialization activities with respect to such Licensed Candidate or Licensed Product, which transition may include a transfer of Regulatory Materials, assignment of clinical trial agreements, transfer of biological materials, transitional distributor or supply arrangement, transfer or assignment of certain Trademarks, or a non-exclusive, royalty-bearing license under Licensee IP and other Patents or Know-How then used by or on behalf of Licensee or its Affiliate in connection with the Development or Commercialization of a Licensed Candidate or Licensed Product, in each case, as applicable and mutually agreed, to Research, Develop, Manufacture, or Commercialize such Licensed Candidate or a Licensed Product (including any improvements, modifications, or enhancements to any such candidate or product). If Relay delivers such notice to Licensee within [***] after the Termination Date, then Licensee and Relay shall meet and negotiate in good faith for the appropriate license, financial and other terms and conditions for Relay to receive (i) a transition of ongoing Development or Commercialization activities with respect to such Licensed Candidate or Licensed Product to Relay, which transition may include a transfer of Regulatory Materials, assignment of clinical trial agreements, transfer of biological materials, transitional distributor or supply arrangement, or a transfer or assignment of certain Trademarks, as applicable, or (ii) a non-exclusive, sublicensable (through multiple tiers, subject to the provisions of Section 12.2 (mutatis mutandis)), non-transferable (except as set forth in Section 18.3 (mutatis mutandis)), worldwide, royalty-bearing license under Licensee IP and other Patents or Know-How then used by or on behalf of Licensee or its Affiliate in connection with the Development or Commercialization of the Terminated Other Licensed Product, in each case, to Research, Develop, Manufacture or Commercialize such Licensed Candidate or Licensed Product (and all improvements, modifications and enhancements to such candidates and products). Notwithstanding the foregoing, neither Party shall be obligated to enter into an agreement for any such transition or license if the Parties are unable in good faith to agree on mutually acceptable terms and conditions.

16.8.3 Termination Pursuant to Section 16.7. In the event of termination of this Agreement with respect to a particular country pursuant to Section 16.7, then, notwithstanding any provision in this Agreement to the contrary, neither Party will have any obligation to the other Party with respect to the subject matter of this Agreement with respect to the terminated country; provided that Article 13 will survive.

16.9 Discontinuation by Licensee of Development/Commercialization of a Relay Pipeline Combination Eligible Licensed Product included in a Relay Pipeline Combination.

16.9.1 If during the Term, Licensee or its Affiliates makes a decision through a governance committee ([***] or their respective equivalent if such committees do not exist in the

future), to permanently cease all Development and Commercialization activities and Manufacturing activities with respect to a Relay Pipeline Combination Eligible Licensed Product, and at such time Relay has ongoing Development or Commercialization activities with respect to the Combination Use of such Relay Pipeline Combination Eligible Licensed Product then Licensee will notify Relay in writing of such cessation and the date of such decision (a "**Relay Pipeline Combination Eligible Licensed Product Discontinuation Notice**"). In the event that (a) Licensee sends Relay a Relay Pipeline Combination Eligible Licensed Product Discontinuation Notice with respect to a Relay Pipeline Combination Eligible Licensed Product and at such time Relay or any of its Affiliates or any Relay Sublicensee has ongoing Development or Commercialization activities with respect to the Combination Use of such Relay Pipeline Combination Eligible Licensed Product in a Relay Pipeline Combination or (b) a Relay Pipeline Combination Eligible Licensed Product Cessation occurs with respect to a Relay Pipeline Combination Eligible Licensed Product, and at such time Relay or any of its Affiliates or any Relay Sublicensee has ongoing Development or Commercialization activities with respect to the Combination Use of such Relay Pipeline Combination Eligible Licensed Product in a Relay Pipeline Combination (such Relay Pipeline Combination Eligible Licensed Product in the case of (a) or (b), a "**Discontinued Relay Pipeline Combination Eligible Licensed Product**"), then, in each case ((a) and (b)), Relay may notify Licensee in writing that it (through itself, an Affiliate or a Relay Sublicensee) wishes to continue Development or Commercialization activities with respect to such Discontinued Relay Pipeline Combination Eligible Licensed Product. A "**Relay Pipeline Combination Eligible Licensed Product Cessation**" means that Licensee, its Affiliates and Licensee Sublicensees have not conducted any Research, Development, Manufacturing or Commercialization activities with respect to such Relay Pipeline Combination Eligible Licensed Product for a continuous period of [***]; provided that (i) if such cessation is a result of a Third Party Action, safety concern, force majeure, injunction or other operation of law, any action by any Regulatory Authority that prevents, limits or otherwise adversely affects any such Research, Development, Manufacturing, or Commercialization activity, including for safety or Manufacturing issues, or any material breach by Relay or any of its Affiliates of its obligations under this Agreement or the SAE Management Plan, the Quality Agreement, the Pharmacovigilance Agreement, the Supply Agreement or any Coordinated Promotion Agreement, such [***] period will be extended for each day any of the foregoing listed in this clause (i) caused such cessation and (ii) if such cessation of activity is due to a Manufacturing issue other than as described in clause (i) and Licensee is using Commercially Reasonable Efforts to seek to remedy such issue, such [***] period will be extended for a reasonable period of time as is reasonably necessary to resolve the Manufacturing issue.

16.9.2 If Relay delivers such written notice under Section 16.9.1 to Licensee within [***] after receipt of the Relay Pipeline Combination Eligible Licensed Product Discontinuation Notice or Relay becoming aware of the occurrence of the Relay Pipeline Combination Eligible Licensed Product Cessation, as applicable, Licensee and Relay shall meet and negotiate in good faith the appropriate license, financial and other terms and conditions for Relay to receive (a) a transition of ongoing Development or Commercialization activities with respect to such Discontinued Relay Pipeline Combination Eligible Licensed Product to Relay, [***], or (b) a non-exclusive, sublicensable (through multiple tiers, subject to the provisions of Section 12.2 (mutatis mutandis)), non-transferable (except as set forth in Section 18.3 (mutatis mutandis)), worldwide, royalty-bearing license under the Relay IP and Licensee IP and other Patents or Know-How then used by or on behalf of Licensee or its Affiliate in connection with the Development, Manufacture

or Commercialization of the Discontinued Relay Pipeline Combination Eligible Licensed Product, in each case, to Research, Develop, Manufacture or Commercialize such Discontinued Relay Pipeline Combination Eligible Licensed Product for Combination Use in Relay Pipeline Combinations (the license, financial and other terms and conditions described in this sentence, the "**Discontinued Relay Pipeline Combination Eligible Licensed Product Terms**"). For clarity, the licenses under this Section shall not include any licenses that Licensee has with a Third Party under which Licensee or its Affiliates would incur financial obligations to such Third Party (unless Relay agrees to bear such financial obligations) or for which such grant would be prohibited or unduly burdensome to Licensee (unless the Parties are able to negotiate a mutually acceptable solution to address such burden on Licensee). In negotiating the Discontinued Relay Pipeline Combination Eligible Licensed Product Terms, the Parties shall take into account the value of the applicable Licensee IP and contribution made by Licensee to the Development and Commercialization of the Discontinued Relay Pipeline Combination Eligible Licensed Product.

16.9.3 If the Relay Pipeline Combination that includes the Discontinued Relay Pipeline Combination Eligible Licensed Product is in Development at the time of Relay's timely delivery of written notice of desire to continue Development or Commercialization activities with respect to such Discontinued Relay Pipeline Combination Eligible Licensed Product under Section 16.9.1, then from such date until agreement by the Parties to Discontinued Relay Pipeline Combination Eligible Licensed Product Terms or final resolution of baseball-style binding arbitration with respect to such Discontinued Relay Pipeline Combination Eligible Licensed Product Terms pursuant to Section 16.10 (the "**Transition Period**") Licensee will continue to Manufacture and supply the clinical supply of such Discontinued Relay Pipeline Combination Eligible Licensed Product to Relay pursuant to the Supply Agreement, or if Licensee fails to do so Relay shall have the remedies set forth in the Supply Agreement. If Commercialization activities have commenced with respect to the Relay Pipeline Combination that includes the Discontinued Relay Pipeline Combination Eligible Licensed Product at the time of Relay's timely delivery of written notice of desire to continue Development or Commercialization activities with respect to such Discontinued Relay Pipeline Combination Eligible Licensed Product under Section 16.9.1, then during the Transition Period Licensee will have the option to continue to Manufacture and book sales for the commercial supply of such Discontinued Relay Pipeline Combination Eligible Licensed Product and to continue to conduct coordinated promotional activities with respect thereto in accordance with the applicable Coordinated Promotion Agreement. If Licensee notifies Relay that it will not continue to Manufacture and book sales for the commercial supply of such Discontinued Relay Pipeline Combination Eligible Licensed Product and to continue to conduct coordinated promotional activities with respect thereto in accordance with the applicable Coordinated Promotion Agreement, or if Licensee materially fails to do so, Licensee hereby grants to Relay and its Affiliates, solely for the Transition Period, a non-exclusive, sublicensable (through multiple tiers), non-transferrable (except as set forth in Section 18.3), royalty-free license under the Relay IP and the Licensee IP to Manufacture and Commercialize the Discontinued Relay Pipeline Combination Eligible Licensed Products in the Field in the Territory, at its sole cost and expense; provided that such license is exercisable beginning on such notice from Licensee or Licensee's material failure to Manufacture and book sales for the commercial supply of such Discontinued Relay Pipeline Combination Eligible Licensed Product and to continue to conduct coordinated promotional activities with respect thereto in accordance with the applicable Coordinated Promotion Agreement.

16.10 Baseball Arbitration. If the Parties are unable to agree on (a) terms and conditions for a Supply Agreement pursuant to Section 7.2.4 ("**Supply Agreement Terms**") within one hundred and [***] after the Effective Date, (b) Terminated Relay Pipeline Combination Eligible Licensed Product Terms within [***] following timely notice from Relay pursuant to Section 16.8.2(b) indicating that Relay wants to negotiate the Terminated Relay Pipeline Combination Eligible Licensed Product Terms, or (c) Discontinued Relay Pipeline Combination Eligible Licensed Product Terms within [***] following timely notice from Relay pursuant to Section 16.9.2 indicating that Relay wants to negotiate the Discontinued Relay Pipeline Combination Eligible Licensed Product Terms (each such period in (a), (b) or (c), the applicable "**Negotiation Period**"), then such Dispute will be subject to final resolution by baseball-style binding arbitration in accordance with the following procedures:

16.10.1 Relay shall notify Licensee of its decision to initiate the arbitration pursuant to this Section 16.10 through written notice to Licensee within [***] following expiration of the applicable Negotiation Period.

16.10.2 Within [***] following Licensee's receipt of such notice, each Party shall appoint one Expert, and the two Experts so selected shall appoint a third Expert within [***] of their nomination, and such final Expert shall act as the chair of the three Expert panel.

16.10.3 Within [***] after the appointment of the final Expert, such Expert shall set a date for the arbitration, which date shall be no more than [***] after the date Relay notified Licensee of its decision to initiate the arbitration under Section 16.10.1.

16.10.4 The arbitration shall be "baseball-style" arbitration; accordingly, at least [***] prior to the arbitration, each Party shall provide the Experts and the other Party with the Terminated Relay Pipeline Combination Eligible Licensed Product Terms, Discontinued Relay Pipeline Combination Eligible Licensed Product Terms or Supply Agreement Terms, as applicable, proposed by it (its "**Proposed Terms**").

16.10.5 In addition, at least [***] in advance of the arbitration, each Party may submit to the Experts and the other Party a revised version of its Proposed Terms (together with a redline showing the changes from the prior draft of its Proposed Terms). The Parties' briefs may include or attach relevant exhibits in the form of documentary evidence, any other material voluntarily disclosed to the submitting Party in advance, or publicly available information. Neither Party may have any other communications (either written or oral) with the Experts other than for the sole purpose of engaging the Experts or as expressly permitted in this Section 16.10.

16.10.6 The arbitration shall consist of [***] hearing of no longer than eight (8) hours, such time to be split equally between the Parties, in the form of presentations by counsel or employees and officers of the Parties. No live witnesses shall be permitted.

16.10.7 No later than [***] following the arbitration, the Experts shall issue their written decision. The Experts shall select one Party's revised Proposed Terms as their decision and shall not have the authority to render any substantive decision other than to select the Proposed Terms submitted by either Licensee or Relay. The Experts shall have no discretion or authority with respect to modifying the positions of the Parties. The Experts' decision shall by a majority

vote of the Experts and such decision shall be final and binding on the Parties and the written agreement selected by the Experts shall constitute a binding agreement between the Parties that may be enforced in accordance with its terms. Each Party shall bear its own costs and expenses in connection with such arbitration and shall share equally the fees and expenses of the Experts. Within [***] following the decision of the Experts, the Parties will execute the winning Proposed Terms.

16.10.8 The violation of one of the time limits specified in this Section 16.10 by the Experts shall not affect the Experts' competence to decide on the subject matter and shall not affect the final and binding decision rendered by the Experts, unless otherwise agreed by the Parties.

16.10.9 The "baseball-style" arbitration in this Section 16.10 shall be the exclusive remedy of either Party if the Parties cannot agree on the Terminated Relay Pipeline Combination Eligible Licensed Product Terms, Discontinued Relay Pipeline Combination Eligible Licensed Product Terms or Supply Agreement Terms, as applicable

16.11 Surviving Provisions.

16.11.1 Accrued Rights; Remedies. Termination or expiration of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of any Party prior to such termination or expiration, and any and all damages or remedies (whether in law or in equity) arising from any breach hereunder, each of which will survive termination or expiration of this Agreement, including any payments that are payable prior to the effective date of termination. Except as otherwise expressly set forth in this Agreement, the termination provisions of this Article 16 are in addition to any other relief and remedies available to either Party under this Agreement and at law or in equity.

16.11.2 Survival. Without limiting the provisions of Section 16.11.1, the rights and obligations of the Parties set forth in the following Sections and Articles of this Agreement will survive the expiration or termination of this Agreement, for the time period specified therein and, if no such time period is specified, indefinitely: Sections 11.13.5, 11.15, 12.1.2 (solely to the extent set forth therein), 12.4, 12.7, 12.8 (with respect to Joint Collaboration Patents), 12.9 (with respect to Joint Collaboration Patents), 12.10 (with respect to Joint Collaboration Patents), Article 11 (Financial Terms) (with respect to amounts earned but not paid), Article 13 (Confidentiality) (other than Section 13.8), Article 14 (Representations and Warranties; Covenants), Article 15 (Indemnification; Insurance), Article 16 (Term and Termination), and Article 18 (Miscellaneous).

ARTICLE 17.
EFFECTIVE DATE; ANTITRUST AND COMPETITION LAW COMPLIANCE

17.1 Effective Date

. Notwithstanding anything to the contrary contained herein, none of the terms and conditions contained in this Agreement (including the obligation for Licensee to make any payments hereunder) will be effective until the HSR Clearance Date or clearance, approval, or expiration or termination of the waiting period under any other applicable Antitrust Law (the later of such date or the Execution Date, the "**Effective Date**"). The Parties acknowledge

that the HSR waiting period for this Agreement expired November 25, 2020 with no requests from the FTC.

17.2 Antitrust and Competition Law Compliance

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17.2.1 Efforts. Each of Relay and Licensee will use its good faith efforts to eliminate any concern on the part of any Governmental Authority regarding the legality of this Agreement under any Antitrust Law, including, promptly taking all steps to secure government antitrust clearance, subject to Section 16.7, including cooperating in good faith with any government investigation including the prompt production of documents and information demanded by any request for documents and of witnesses if requested. Notwithstanding the foregoing, this Article 17 and the term "good faith efforts" do not require that either Party (a) offer, negotiate, commit to or effect, by consent decree, hold separate order, trust or otherwise, the sale, divestiture, license or other disposition of any capital stock, assets, rights, products or businesses of Relay, Licensee or their respective Affiliates, (b) agree to any restrictions on the businesses of Relay, Licensee or their respective Affiliates, or (c) pay any amount or take any other action to prevent, effect the dissolution of, vacate, or lift any decree, order, judgment, injunction, temporary restraining order, or other order in any suit or proceeding that would otherwise have the effect of preventing or delaying the transactions contemplated by this Agreement.

17.2.2 Merger Control Filings. At the written request of Licensee, each of Relay and Licensee, as appropriate, will, within [***] after receipt of Licensee's written request under this Article 17 (or such later time as may be agreed to in writing by the Parties), file any Merger Control Filing required under any other applicable Antitrust Law in the reasonable opinion of Licensee with respect to the transactions contemplated by this Agreement. The Parties will cooperate with one another to the extent necessary in the preparation of any such Merger Control Filing. Each Party will pay: [***].

17.2.3 Termination for Failure to Obtain Merger Control Clearance. Each of Relay and Licensee will have the right to terminate this Agreement in accordance with Section 16.7.

17.2.4 Information Exchange. Each of Relay and Licensee will, in connection with any Merger Control Filing, (a) reasonably cooperate with each other in connection with any communication, filing or submission and in connection with any investigation or other inquiry, including any proceeding initiated by a private party; (b) keep the other Party or its counsel informed of any communication (and if in writing, provide a copy to the other Party or its counsel) received by such Party from, or given by such Party any Governmental Authority and of any communication received or given in connection with any proceeding by a private party, in each case regarding the transactions contemplated by this Agreement; (c) consult with each other in advance of any meeting or conference with such Governmental Authority or, in connection with any proceeding by a private party, with such private party, and to the extent permitted by the Governmental Authority or such private party, give the Parties or their counsel the opportunity to attend and participate in such meetings and conferences; and (d) permit the other Party or its counsel to review in advance any submission, filing or communication (and documents submitted therewith) intended to be given by any Governmental Authority, or, in connection with any proceeding by a private party, to such private party; provided that materials may be redacted to remove references concerning the valuation of the business of either Party. Relay and Licensee, as each deems advisable and necessary, may reasonably designate any competitively sensitive

material to be provided to the other under this Article 17 as "**Antitrust Counsel Only Material**". Such materials and the information contained therein will be given only to the outside antitrust counsel of the recipient and will not be disclosed by such outside counsel to employees, officers or directors of the recipient unless express permission is obtained in advance from the source of the materials (Relay or Licensee, as the case may be) or the applicable Party's legal counsel.

17.2.5 Assistance. Subject to this Article 17, at the reasonable request of either Party, Relay and Licensee will cooperate and use respectively all reasonable efforts to make all other registrations, filings and applications, to give all notices and to obtain as soon as practicable all governmental or other consents, transfers, approvals, orders, qualifications, authorizations, permits and waivers, if any, and to do all other things necessary or desirable for the consummation of the transactions as contemplated by this Agreement in accordance with applicable Antitrust Laws.

17.3 Obligations Prior to Effective Date

. Subject to Applicable Law, during the period between the Execution Date and the Effective Date:

17.3.1 Conduct of Business Prior to Effective Date. Relay will conduct its business relating to the Licensed Candidates and Licensed Products in, and will not take any action except in, the ordinary course of business and in a manner consistent with past practices. Relay will continue to conduct the Relay Phase Ia Trial in accordance with accepted pharmaceutical industry norms and ethical practices and in accordance with the Relay Phase Ia Plan as disclosed to Licensee prior to the Execution Date. Relay will not (and Relay will ensure that its Affiliates do not) take any action that would conflict with any or limit the scope of any rights or licenses granted to Licensee hereunder, including that it will not (a) assign, transfer, convey, encumber (including any liens or charges) or dispose of, or enter into any agreement with any Third Party to assign, transfer, convey, encumber (including any liens or charges) or dispose of, any Relay IP related to the Licensed Candidates or Licensed Products, or (b) disclose any material information related thereto to any Third Party, in each case ((a) through (b)), if such activity would conflict with any or limit the scope of any rights or licenses granted to Licensee hereunder. For the avoidance of doubt, an assignment of this Agreement in accordance with Section 18.3 will not be a breach of this Article 17; provided that any such assignment does not, or would not reasonably be expect to, have the effect of delaying, impairing, or impeding, the early termination or expiration of any applicable waiting period under Antitrust Law for the transactions contemplated by this Agreement.

ARTICLE 18.
MISCELLANEOUS

18.1 Force Majeure

. Neither Party will be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, pandemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts,

omissions or delays in acting by any Governmental Authority (each a "**Force Majeure Event**"). The non-performing Party will notify the other Party of such Force Majeure Event within [***] after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance will be of no greater scope and no longer duration than is necessary and the non-performing Party will use Commercially Reasonable Efforts to remedy its inability to perform.

18.2 Export Control

. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining such license or other governmental approval from the appropriate agency or other Governmental Authority in accordance with Applicable Law.

18.3 Assignment; Change of Control

.

18.3.1 Except as provided in this Section 18.3, this Agreement may not be assigned otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party, which consent will not be unreasonably withheld.

18.3.2 Licensee may, without consent of Relay, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate of Licensee or in its entirety in connection with a Change of Control. Relay may, without the consent of Licensee, but upon written notice to Licensee, assign this Agreement in whole or in part to an Affiliate of Relay or in its entirety in connection with a Change of Control of Relay, subject to Section 18.3.4.

18.3.3 Any attempted assignment not in accordance with this Section 18.3 will be void. Any permitted assignee will assume all assigned obligations of its assignor under this Agreement. Except as provided under Section 18.3.4, the terms and conditions of this Agreement will be binding upon, and will inure to the benefit of, the Parties and their respected successors and permitted assigns. This Agreement is for the sole benefit of the Parties and not for the benefit of any other Person.

18.3.4 In the event that there is a Change of Control of Relay, then the following provisions will apply and be in full force and effect:

(a) Relay will provide written notice to Licensee on or prior to such Change of Control becoming effective.

(b) If the Acquirer of Relay is Developing or Commercializing a Competitive Product or any other compound or product that is competitive with a [***] Combination, upon Licensee's request, Relay will establish reasonable protections and safeguards to protect against Licensee's Confidential Information regarding Development or Commercialization of Licensed Candidates or Licensed Products (including [***] Combinations) being shared with the personnel of Relay's Acquirer who are materially participating the Development or Commercialization of such Competitive Product or other competitive compound

or product (such protections and safeguards will not extend to personnel at or above supervisory level).

(c) For the avoidance of doubt, upon a Change of Control of Relay:

(i) If Relay's Opt-In Right has not been previously exercised or expired, Relay's Opt-In Right shall not survive a Change of Control of Relay and shall expire upon completion of the Change of Control; and

(ii) if Relay's Opt-In Right has been previously exercised, but Relay's Opt-Out Right has not been previously exercised or expired, the Opt-Out Right shall expire upon the [***] anniversary of the completion of the Change of Control [***]

In the event of any sale, transfer or license by Relay of all or substantially all of its assets or rights relating to one or more of the Relay Pipeline Compounds that are included in a Relay Pipeline Combination, this Section 18.3.4 shall apply to such sale or transfer in the same manner as a Change of Control to the extent applicable, *mutatis mutandis*.

18.4 Performance by Affiliates

. Either Party may discharge any obligations and exercise any right hereunder through any of its Affiliates; provided that such Party will cause its Affiliates to comply with the applicable provisions of this Agreement in connection with such performance and the Party will remain fully responsible and obligated for its obligations hereunder.

18.5 Severability

. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future Applicable Law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision will be fully severable, (b) this Agreement will be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement will remain in full force and effect and will not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid, or unenforceable provision, the Parties will make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering into this Agreement may be realized. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

18.6 Governing Law

. This Agreement will be governed by, and construed in accordance with, the laws of the State of New York, regardless of the laws that might otherwise govern under applicable principles of conflicts of laws thereof.

18.7 Waiver of Right to Trial by Jury

. EACH PARTY HERETO, TO THE EXTENT PERMITTED BY APPLICABLE LAWS, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES. THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE. Each Party hereto (a) certifies that no representative or attorney of any other Party has represented, expressly or otherwise, that such Party would not, in the event of any action or other proceeding arising out of or relating to this Agreement and the transactions it

contemplates, seek to enforce the foregoing waiver and (b) acknowledges that it and the other Party have been induced to enter into this Agreement, by, among other things, the mutual waiver and certifications in this Section 18.7.

18.8 Equitable Relief

Each Party acknowledges and agrees that the restrictions set forth in Article 8, Article 12 and Article 13 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of such Section or Articles may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Section or Articles, the non-breaching Party will be authorized and entitled to seek to obtain injunctive relief, whether preliminary or permanent, specific performance, and an equitable accounting of all earnings, profits, and other benefits arising from such breach, which rights will be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity to prevent such breach or threatened breach of this Agreement and to enforce specifically the terms and provisions of such Section or Articles of this Agreement in a court of competent jurisdiction. Both parties agree to waive any requirement that the other (a) post a bond or other security as a condition for obtaining any such relief, and (b) showing irreparable harm, balancing of harms, consideration of the public interest, or inadequacy of monetary damages as a remedy. Nothing in this Section 18.8 is intended, or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

18.9 Informal Dispute Resolution

.

18.9.1 General. The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights or obligations hereunder, including the interpretation, alleged breach, enforcement, termination or validity of this Agreement (a "**Dispute**"). Matters subject to decision-making pursuant to Section 10.7 or resolution in accordance with Section 16.10 are not subject to this Section 18.9.

18.9.2 Alliance Managers; Escalation to Executive Officers. In the event of the occurrence of such a Dispute, the Parties shall first refer such Dispute to the Alliance Managers for attempted resolution by such Alliance Managers within [***] after such referral. If such Dispute is not resolved within such [***] period, either Party may, by written notice to the other, have such Dispute referred to the Executive Officers, who will confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the Executive Officers will be conclusive and binding on the Parties.

18.9.3 Jurisdiction; Equitable Relief. If the Executive Officers are not able to agree on the resolution of any Dispute within [***] after such Dispute was first referred to them, then, subject to this Section 18.9.3, either Party may initiate arbitration in accordance with Section 18.10 or with respect to any Disputes that involve the validity, infringement or validity of any Patents, such Dispute will be resolved as provided in Section 18.11. Notwithstanding anything herein to the contrary, nothing in this Section 18.9 will preclude either Party from seeking interim equitable relief concerning a Dispute as provided in Section 18.8 or 18.10.5.

18.9.4 [***]. [***].

18.10 Arbitration.

18.10.1 Except as otherwise expressly provided in this Agreement, any Dispute not resolved by the Parties pursuant to Section 18.9 shall be resolved through binding arbitration conducted by the International Chamber of Commerce in accordance with the then prevailing Rules of Arbitration of the International Chamber of Commerce (for purposes of this Section 18.10, the "**Rules**"), except as modified in this Agreement, applying the substantive law specified in Section 18.6.

18.10.2 Each Party shall, within [***] of the initiation of the arbitration, select one (1) arbitrator, and the two (2) arbitrators so selected shall choose a third (3rd) arbitrator within [***] of their election. All three (3) arbitrators shall serve as neutrals and have at least [***] of (a) dispute resolution experience (including judicial experience) and (b) legal or business experience in the biotech or pharmaceutical industry. If a Party fails to nominate its arbitrator, or if the Parties' arbitrators cannot agree on the third (3rd) arbitrator, the necessary appointments shall be made in accordance with the Rules. Once appointed by a Party, such Party shall have no ex parte communication with its appointed arbitrator. The arbitration proceedings shall be conducted [***]. The arbitration proceedings and all pleadings and written evidence shall be in the English language. Any written evidence originally in another language shall be submitted in English translation accompanied by the original or a true copy thereof.

18.10.3 Each Party agrees to use reasonable efforts to make all of its current employees reasonably available, if reasonably needed, and agrees that the arbitrators may determine any person as necessary. The arbitrators shall be instructed and required to render a written, binding, non-appealable resolution and award on each issue that clearly states the basis upon which such resolution and award is made. The written resolution and award shall be delivered to the Parties as expeditiously as possible, but in no event more than [***] after conclusion of the hearing, unless otherwise agreed by the Parties. Judgment upon such award may be entered in any competent court or application may be made to any competent court for judicial acceptance of such an award and order for enforcement. Each Party agrees that, notwithstanding any provision of Applicable Law or of this Agreement, it will not request, and the arbitrators shall have no authority to award, damages that are specifically prohibited pursuant to Section 15.5.

18.10.4 The Parties will share equally the fees and expenses of the arbitrators and bear their own attorneys' fees and associated costs and expenses.

18.10.5 Notwithstanding anything to the contrary in this Section 18.10 or Section 18.9, in the event that a Party reasonably requires relief on a more expedited basis than would be possible pursuant to the procedure set forth in this Section 18.10 or Section 18.9, such Party may seek a temporary injunction or other interim equitable relief in a court of competent jurisdiction pending the ability of the arbitrators to review the decision under this Section 18.10. Such court shall have no jurisdiction or ability to resolve Disputes beyond the specific issue of temporary injunction or other interim equitable relief.

18.10.6 At the request of either Party, the arbitrators shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings.

18.11 Subject Matter Exclusions. Notwithstanding the provisions of Section 18.10, any Dispute not resolved internally by the Parties pursuant to Section 18.9 that involves the validity, infringement or enforceability of a Patent included in a license granted in this Agreement (a) that is issued in the United States shall be subject to actions before the United States Patent and Trademark Office or submitted exclusively to the federal court located in the jurisdiction of the district where any of the defendants reside and (b) that is issued in any other country (or region) shall be brought before an appropriate regulatory or administrative body or court in that country (or region), and in all cases, the Parties hereby consent to the jurisdiction and venue of such courts and bodies.

18.12 Notices

. Any notice, request, demand, waiver, consent, approval, or other communication permitted or required under this Agreement will be in writing, will refer specifically to this Agreement and will be deemed given only if delivered by hand or sent by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in this Section 18.10 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 18.10. Such notice will be deemed to have been given as of the date delivered by hand or on the [***] (at the place of delivery) after deposit with an internationally recognized overnight delivery service. This Section 18.10 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

If to Licensee, to:

[***]

If to Relay, to:

Relay Therapeutics, Inc.
399 Binney Street
2nd Floor
Cambridge, MA 02139
Attention: Chief Executive Officer

with a copy (which will not constitute notice) to:
Goodwin Procter, LLP
100 Northern Avenue
Boston, MA 02210
Attention: Kingsley L. Taft, Ph.D., Esq.

18.13 Entire Agreement

. This Agreement, together with the Schedules expressly contemplated hereby and attached hereto, contains the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior agreements or understandings between the Parties with respect to the subject matter hereof. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. The Parties agree that they have been represented by counsel during the negotiation, drafting, preparation and execution of this Agreement and, therefore, waive the application of any

Applicable Law or rule of construction providing that ambiguities in an agreement or other document will be construed against the party drafting such agreement or document.

18.14 English Language

. This Agreement will be written and executed in, and all other communications under or in connection with this Agreement will be in, the English language. Any translation into any other language will not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version will control.

18.15 Amendments and Waivers

. No modification, amendment or waiver of any provision of, or consent or approval required by, this Agreement will be effective unless it is in writing and signed by an authorized representative of both Parties. Such modification, amendment, waiver, consent or approval will be effective only in the specific instance and for the purpose for which given. Neither the failure of either Party to enforce, nor the delay of either Party in enforcing, any condition or part of this Agreement at any time will be construed as a waiver of that condition or part or forfeit any rights to future enforcement thereof. No action taken pursuant to this Agreement, including any investigation by or on behalf of either Party, will be deemed to constitute a waiver by the Party taking action of compliance by the other Party with any representation, warranty, covenant, agreement or obligation contained herein.

18.16 Cumulative Rights

. Except as expressly provided herein, the various rights under this Agreement will be construed as cumulative, and no one of them is exclusive of any other or exclusive of any rights allowed by Applicable Law.

18.17 Benefits of Agreement

. All of the terms and provisions of this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. Except as set forth in Article 15, this Agreement is for the sole benefit of the Parties and not for the benefit of any other Person.

18.18 Further Assurance

. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement.

18.19 Relationship of the Parties

. It is expressly agreed that Licensee, on the one hand, and Relay, on the other hand, will be independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture, or agency. Neither Licensee, on the one hand, nor Relay, on the other hand, will have the authority to make any statements, representations, or commitments of any kind, or to take any action, which will be binding on the other, without the prior written consent of the other Party to do so. All Persons employed by a Party will be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment will be for the account and expense of such Party.

18.20 Counterparts

. This Agreement may be executed in two counterparts, and each such counterpart hereof will be deemed to be an original instrument, but both such counterparts together will constitute but one agreement. Delivery of an executed counterpart of a signature page of this Agreement by email or other electronic transmission will be effective as delivery of a manually executed original counterpart of this Agreement.

18.21 Schedules

. In the event of any inconsistencies between this Agreement and any Schedules or other attachments hereto, the terms of this Agreement will control.

18.22 Descriptive Headings

. Descriptive headings are for convenience only and will not control or affect the meaning or construction of any provision of this Agreement.

18.23 Certain Interpretations

. Except as otherwise expressly provided in this Agreement or as the context otherwise requires, the following rules of interpretation apply to this Agreement: (a) the singular includes the plural and the plural includes the singular; (b) "or" and "any" are not exclusive, "or" means "and/or" and the words "include" and "including," and variations thereof, will not be deemed to be terms of limitation, but rather will be deemed to be followed by the words "without limitation;" (c) the terms "will" and "shall" will be deemed to have the same meaning; (d) a reference to any contract includes permitted supplements and amendments; (e) a reference to Applicable Law includes any amendment or modification to such Applicable Law; (f) a reference to a Person includes its successors, heirs and permitted assigns; (g) a reference to one gender will include any other gender; (h) a reference in this Agreement to an Article, Section or Schedule is to the referenced Article, Section or Schedule of this Agreement, unless expressly specified otherwise; (i) "hereunder," "hereof," and words of similar import will be deemed references to this Agreement as a whole and not to any particular Article, Section or other provision; (j) unless otherwise provided herein, any reference to "days" means calendar days; (k) "extent" in the phrase "to the extent" means the degree to which a subject or other thing extends, and such phrase does not necessarily mean simply "if"; (l) the phrase "non-refundable and non-creditable" will in no way limit either Party's right to pursue or receive damages in connection with any breach of this Agreement; and (m) a list or phrases with an oxford comma shall be read in the same way as a list without an oxford comma.

[Signature Page Follows]

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have caused this COLLABORATION AND LICENSE AGREEMENT to be executed by their respective duly authorized representatives as of the Execution Date.

GENENTECH, INC.

By:/s/ Edward Harrington

Name: Edward Harrington

Title:CFO, Genentech

RELAY THERAPEUTICS, INC.

By:/s/ Sanjiv Patel

Name: Sanjiv Patel

Title:CEO

F. HOFFMANN-LA ROCHE LTD

By:/s/ Stefan Arnold

Name: Stefan Arnold

Title:Head Legal Pharma

F. HOFFMANN-LA ROCHE LTD

By:/s/ Vikas Kabra

Name:Vikas Kabra

Title:Head Transaction Excellence

SCHEDULE 1.102

GLOBAL DEVELOPMENT PLAN

GLOBAL DEVELOPMENT PLAN

[***]

Schedule 1.262

Technology Transfer Plan

Exhibit A

[***]

Exhibit B

Know-How and Materials (Manufacture Transfer)

[***]

Schedule 3.2.3

Transfer of Sponsor Obligations

[***]

Schedule 3.3

RELAY PHASE IA PLAN

[***]

Schedule 3.4.1

Delegation of Authority

[***]

Schedule 11.4.1

Example Net Profits and Net Losses Calculations

[***]

Schedule 13.5

PRESS RELEASE

Relay Therapeutics Announces a Worldwide License and Collaboration Agreement with Genentech for RLY-1971

Collaboration brings together clinical stage SHP2 and KRAS G12C inhibitors

Relay Therapeutics will receive $75 million upfront and is eligible to receive an additional $25 million in near-term payments and $695 million in additional potential milestones, plus royalties on global net product sales

Relay Therapeutics to host conference call at 8:00 a.m. ET

Cambridge, MA – December 14, 2020 – Relay Therapeutics, Inc. (Nasdaq: RLAY), a clinical-stage precision medicine company transforming the drug discovery process by leveraging unparalleled insights into protein motion, today announced it has entered into a worldwide license and collaboration agreement with Genentech, a member of the Roche Group, for the development and commercialization of RLY-1971, a potent inhibitor of SHP2. Under the collaboration, Genentech will assume development of RLY-1971 with the potential to expand into multiple combination studies including with Genentech's investigational inhibitor of KRAS G12C, GDC-6036.

"RLY-1971 has the potential to serve as a backbone for combination therapy across numerous solid tumors and therefore represents an encouraging approach for cancer patients," said Sanjiv Patel, M.D., president and chief executive officer of Relay Therapeutics. "Roche and Genentech's global footprint and deep expertise in oncology makes them the perfect partner for us to execute the broad development and commercialization of RLY-1971."

"Genentech has a longstanding commitment to understanding the underlying biology of KRAS, the most commonly mutated oncogene and an important driver of cancer growth," said James Sabry, M.D., Ph.D., global head of pharma partnering, Roche. "We are excited to partner with Relay Therapeutics, and we believe that the combination of KRAS G12C and SHP2 inhibitors together represents a promising approach that we hope could become a new treatment option for patients with KRAS G12C mutant tumors."

Under the terms of the agreement, Relay Therapeutics will receive $75 million in an upfront payment and is eligible to receive $25 million in additional near-term payments. Relay Therapeutics also has the right to opt in to a 50/50 U.S. profit/cost share on RLY-1971. If Relay elects to opt in, then Relay will be eligible to receive 50 percent of profits from U.S. sales and up to $410 million in additional ex-U.S. commercialization and sales-based milestone payments, as well as royalties on ex-U.S. net sales. If Relay Therapeutics elects not to opt in, then Relay will be eligible to receive up to $695 million in additional development, commercialization and sales-based milestones, as well as royalties on global net sales, anticipated to be in the low-to-mid-teens. In the event of regulatory approval of both RLY-1971 and GDC-6036 in combination, Relay Therapeutics is eligible to receive additional royalties. Relay Therapeutics retains the right to combine RLY-1971 with its selective FGFR2 and mutant-selective PI3Kα programs.

With the execution of this collaboration, Relay Therapeutics anticipates it will have cash and investments to sustain its operations through 2024.

Conference Call Information

Relay Therapeutics will host a live webcast today beginning at 8:00 a.m. ET to discuss the collaboration. To access the live call, please dial 1 (833) 540-1168 (domestic) or 1 (929) 517-0359 (international) and refer to conference ID 8792127. A webcast of the conference call will be available under "News and Presentations" in the Investors & Media section of Relay Therapeutics' website at http://ir.relaytx.com. The archived webcast will be available on Relay Therapeutics' website approximately two hours after the conference call and will be available for 30 days following the call.

About RLY-1971

RLY-1971 is a potent small molecule inhibitor of Src homology region 2 domain-containing phosphatase-2 (SHP2). SHP2 is a critical signaling node and regulator that promotes cancer cell survival and growth through the RAS pathway, playing a key role in the way cancer cells develop resistance to targeted therapies. Preclinically, RLY-1971 demonstrated significant anti-tumor activity as a monotherapy in cancers with specific alterations as well as in combination with other anti-tumor agents, potentially overcoming or delaying the onset of resistance to those therapies. RLY-1971 is currently being evaluated in a first-in-human trial designed to treat patients with advanced or metastatic solid tumors. To learn more about the first-in-human clinical trial of RLY-1971, please visit here.

About Relay Therapeutics

Relay Therapeutics (Nasdaq: RLAY) is a clinical-stage precision medicines company transforming the drug discovery process with the goal of bringing life-changing therapies to patients. Built on unparalleled insights into protein motion and how this dynamic behavior relates to protein function, Relay Therapeutics aims to effectively drug protein targets that have previously been intractable, with an initial focus on enhancing small molecule therapeutic discovery in targeted oncology. The Company's Dynamo platform integrates an array of leading-edge experimental and computational approaches to provide a differentiated understanding of protein structure and motion to drug these targets. For more information, please visit www.relaytx.com or follow us on Twitter.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding the expected strategic benefits of the collaboration; the receipt of upfront and near-term payments and potential milestone and royalty payments under the collaboration; the potential of RLY-1971, including in combination with Genentech's GDC-6036; the potential therapeutic benefits of inhibiting KRAS G12C and SHP2 in combination; the Company's strategy, business plans and focus; and expectations regarding our cash runway. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these

identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: the impact of COVID-19 on countries or regions in which we have operations or do business, as well as on the timing and anticipated results of our clinical trials, strategy and future operations; the delay of any current or planned clinical trials or the development of the Company's drug candidates, including, but not limited to, RLY-1971 and RLY-4008; the risk that the results of our clinical trials may not be predictive of future results in connection with future clinical trials; the Company's ability to successfully demonstrate the safety and efficacy of its drug candidates; the timing and outcome of the Company's planned interactions with regulatory authorities; and obtaining, maintaining and protecting its intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Relay Therapeutics' Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Relay Therapeutics' views only as of today and should not be relied upon as representing its views as of any subsequent date. Relay Therapeutics explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Contact:
Pete Rahmer, Head of Investor Relations and Communications
617-322-0715
prahmer@relaytx.com

Media:
Dan Budwick
1AB
973-271-6085
dan@1abmedia.com

Schedule 14.2

Exceptions to Representations and Warranties of Relay

[***]

Exhibit 21.1

SUBSIDIARIES

Subsidiary	**Jurisdiction of Incorporation**
Relay Securities Corporation	Massachusetts

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-239912) pertaining to the 2020 Stock Option and Incentive Plan, and 2020 Employee Stock Purchase Plan of Relay Therapeutics, Inc. of our report dated March 25, 2021, with respect to the consolidated financial statements of Relay Therapeutics, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 25, 2021

Exhibit 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

I, Sanjiv K. Patel, certify that:

1. I have reviewed this Annual Report on Form 10-K of Relay Therapeutics, Inc.;

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

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2021

By: /s/ Sanjiv K. Patel
Sanjiv K. Patel
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 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

I, Thomas Catinazzo, certify that:

1. I have reviewed this Annual Report on Form 10-K of Relay Therapeutics, Inc.;

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

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2021

By: /s/ Thomas Catinazzo
Thomas Catinazzo
Senior Vice President, Finance
(Principal Accounting Officer and
Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Relay Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of their knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 25, 2021

By: /s/ Sanjiv K. Patel
Sanjiv K. Patel
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 25, 2021

By: /s/ Thomas Catinazzo
Thomas Catinazzo
Senior Vice President, Finance
(Principal Accounting Officer and Principal Financial Officer)