# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 10-K

$\boxtimes$	ANNUAL REPORT PURSUANT TO SECTION 1	13 OR 15(d) OF THE SECURITIES EXCHANG or the fiscal year ended December 31, 2019 OR	GE ACT OF 1934	
	TRANSITION REPORT PURSUANT TO SECTI	ON 13 OR 15(d) OF THE SECURITIES EXCH	IANGE ACT OF 1934	
		RANSITION PERIOD FROMTO Commission File Number: 001-37490		
		ra Oncology, Inc.		
	(LAGCE)	ianic of registrant as specified in its charter)		
	Delaware (State or other jurisdiction of incorporation or organization)		20-0138994 LR.S. Employer tification Number)	
	c/o 2150 – 885 West Georgia Street Vancouver, British Columbia, Canada (Address of principal executive offices)		V6C 3E8 (Zip Code)	
	(Regist	(604) 558-6536 rant's telephone number, including area code)		
	Securities	s registered pursuant to Section 12(b) of the Act:		
		(-)	Name of each exchange on which	
	<u>Title of each class</u> Common Stock, \$0.001 par value	Trading Symbol(s) SRRA	registered The Nasdaq Stock Market LLC	
	•	gistered pursuant to Section 12(g) of the Act: None	The Nasuay Stock Market LLC	
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Indic	cate by check mark if the Registrant is a well-known seasoned issuer,	as defined in Rule 405 of the Securities Act. YES \( \square\) NO \( \sqrt{2} \)	₫	
Indic	cate by check mark if the Registrant is not required to file reports purs	suant to Section 13 or 15(d) of the Act. YES $\square$ NO $\boxtimes$		
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	cate by check mark whether the Registrant has submitted electronicall chapter) during the preceding 12 months (or for such shorter period th			05 of
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Non-	-accelerated filer ⊠		Smaller reporting company	$\boxtimes$
	emerging growth company, indicate by check mark if the registrant h dards provided pursuant to Section 13(a) of the Exchange Act. ⊠	nas elected not to use the extended transition period for complyi	Emerging growth company ng with any new or revised financial accounting	⊠ ng
Indic	cate by check mark whether the Registrant is a shell company (as defi	ned in Rule 12b-2 of the Exchange Act). YES $\square$ NO $\boxtimes$		
	aggregate market value of common stock held by non-affiliates of the daq Global Market on June 28, 2019, the last business day of the regis			e
The	number of shares of Registrant's Common Stock outstanding as of Fe			
	DOCU	IMENTS INCORPORATED BY REFERENCE		

Portions of the Registrant's Definitive Proxy Statement ("Proxy Statement") relating to the 2020 Annual Meeting of Stockholders will be filed with the Commission within 120 days after the end of the Registrant's 2019 fiscal year and is incorporated by reference into Part III of this Report.

## TABLE OF CONTENTS

		Page
PART I		
Item 1.	<u>Business</u>	2
Item 1A.	Risk Factors	26
Item 1B.	<u>Unresolved Staff Comments</u>	76
Item 2.	<u>Properties</u>	76
Item 3.	<u>Legal Proceedings</u>	76
Item 4.	Mine Safety Disclosures	76
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	77
Item 6.	Selected Consolidated Financial Data	77
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	79
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	89
Item 8.	Consolidated Financial Statements and Supplementary Data	90
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	117
Item 9A.	Controls and Procedures	117
Item 9B.	Other Information	118
PART III		
Item 10.	<u>Directors, Executive Officers and Corporate Governance</u>	119
Item 11.	Executive Compensation	119
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	119
Item 13.	Certain Relationships and Related Transactions, and Director Independence	119
Item 14.	Principal Accounting Fees and Services	119
PART IV		
Item 15.	Exhibits, Consolidated Financial Statement Schedules	120
Item 16.	Form 10-K Summary	123
	<u>Signatures</u>	124

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (Annual Report) contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act), and section 27A of the Securities Act of 1933, as amended (Securities Act). All statements contained in this Annual Report other than statements of historical fact, including statements regarding our future clinical development activities, expected timing and results of clinical trials, future results of operations and financial position, our business strategy and plans and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect," and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Item 1A, "Risk Factors" and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements to conform these statements to actual results or to changes in our expectations, except as required by law. You should read this Annual Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Unless the context indicates otherwise, as used in this Annual Report, the terms "Sierra Oncology," "the Company," "we," "us" and "our" refer to Sierra Oncology, Inc., a Delaware corporation, and its subsidiaries taken as a whole, unless otherwise noted. Sierra Oncology is our registered trademark. The "Sierra Oncology" logo and all product names are our common law trademarks. This Annual Report contains additional trade names, trademarks and service marks of other companies, which are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

#### PART I

### Item 1. Business.

#### Overview

We are a late stage drug development company focused on advancing our lead product candidate, momelotinib, a potent, selective and orally-bioavailable JAK1 (Janus kinase 1), JAK2 (Janus kinase 2) and ACVR1 (Activin A receptor type 1) inhibitor with a potentially differentiated therapeutic profile for the treatment of myelofibrosis. We have a highly experienced management team with a proven track record of success in hematology and oncology drug development. We are oriented towards achieving the successful registration and commercialization of momelotinib.

During the third quarter of 2018, we acquired momelotinib from Gilead Sciences, Inc. (Gilead). Momelotinib has been investigated in two completed Phase 3 trials for the treatment of myelofibrosis. Data from these trials indicate a potentially differentiated therapeutic profile encompassing anemia-related clinical benefits, as well as achieving constitutional symptom control benefits and substantive splenic volume reductions (see additional discussion below under Momelotinib – A Potent and Selective JAK1, JAK2 and ACVR1 Inhibitor).

In December 2018, we reported new data for momelotinib collated from the two completed SIMPLIFY Phase 3 clinical trials and a translational biology study in transfusion dependent patients with myelofibrosis. Data from the latter study were also concurrently presented in a poster at the 60<sup>th</sup> American Society of Hematology Annual Meeting & Exposition in San Diego, California. We reported aggregated transfusion independence responses from more than 150 intermediate and high-risk transfusion dependent myelofibrosis patients demonstrating robust and consistent response rates within and across the clinical studies. More than 44% of these patients became transfusion free for at least 12 weeks and nearly 50% were transfusion independent for at least 8 weeks.

In the second quarter of 2019, we announced that we had obtained regulatory clarity with the U.S. Food and Drug Administration (FDA) concerning the design of a Phase 3 clinical trial intended to support potential registration of momelotinib. We also announced that the FDA had granted Fast Track designation to momelotinib for the treatment of patients with intermediate/high-risk myelofibrosis who have previously received a JAK inhibitor.

Following receipt of this clarity, we announced the design of the MOMENTUM Phase 3 clinical trial in myelofibrosis, which we subsequently launched in the fourth quarter of 2019. MOMENTUM is a randomized double-blind trial designed to enroll 180 myelofibrosis patients who are symptomatic and anemic and have been treated previously with a JAK inhibitor. The Primary Endpoint of the trial is the Total Symptom Score (TSS) response rate of momelotinib compared to danazol at Week 24 (99% power; p-value < 0.05). Danazol has been selected as an appropriate treatment comparator given its use to ameliorate anemia in myelofibrosis patients, as recommended by National Comprehensive Cancer Network (NCCN) and European Society for Medical Oncology (ESMO) guidelines. Patients will be randomized 2:1 to receive either momelotinib or danazol. After 24 weeks of treatment, patients on danazol will be allowed to crossover to receive momelotinib.

During the fourth quarter of 2019, we reported new analyses of red blood cell (RBC) transfusion data from SIMPLIFY-1, a double-blind Phase 3 trial of momelotinib head-to-head versus ruxolitinib in JAK inhibitor naïve patients, which were presented in a poster by Dr. Ruben Mesa, Director of the Mays Cancer Center, home to UT Health San Antonio MD Anderson Cancer Center, at the 61st American Society of Hematology (ASH) Annual Meeting in Orlando, Florida. These analyses demonstrated that patients who received momelotinib had significantly decreased transfusion requirements compared to those treated with ruxolitinib, including an odds ratio of nearly 10 for receiving no transfusions during the 24-week study period. Transfusion dependency and moderate to severe anemia are critical negative prognostic factors for overall survival in myelofibrosis.

Our portfolio also includes two DNA Damage Response (DDR) assets, consisting of SRA737 and SRA141:

• SRA737 is our potent, highly selective, orally bioavailable small molecule inhibitor of Checkpoint kinase 1 (Chk1). Chk1 is a key regulator of cell cycle progression and the DDR network. SRA737 is

being evaluated across multiple indications in two Phase 1/2 trials, as monotherapy and when potentiated by non-cytotoxic low-dose gemcitabine (LDG), a potent extrinsic inducer of replication stress. At the 2019 American Society of Clinical Oncology (ASCO) annual meeting, we reported preliminary data from these trials, which included anti-cancer activity across multiple indications.

• SRA141 is our potent, selective, orally bioavailable small molecule inhibitor of Cell division cycle 7 kinase (Cdc7). We successfully completed the IND filing process with the FDA for SRA141 in 2018.

We wholly own momelotinib, subject to future milestone payments and royalties (see "Asset Purchase Agreement" below), and retain the global commercialization rights to SRA737 and SRA141.

#### Our Lead Product Candidate - Momelotinib

### Myelofibrosis

Myelofibrosis is a disorder involving the stem-cells that give rise to blood cells, and is driven by molecular abnormalities that activate the JAK-signal transducers and activators of transcription (JAK-STAT) pathway. The Janus kinases (JAKs) play a central role in the regulation of blood cell production, controlling survival, proliferation, and differentiation of progenitor cells as well as the function of mature cells. Abnormal activation of the JAK-STAT pathway is central to the development of myelofibrosis by driving proliferation, inflammation, fibrosis, and progression of disease.

The three cardinal disease manifestations of myelofibrosis are (1) progressive anemia, often in association with thrombocytopenia (deficiency of platelets in the blood) or other cytopenias (blood cell deficiencies); (2) constitutional symptoms such as fatigue, night sweats, fever, cachexia (wasting), bone pain, pruritus (itching), and weight loss; and (3) organ enlargement, principally of the spleen and less often the liver, due to these organs attempting to produce blood cells, which can cause commonly associated symptoms such as abdominal distension and pain, early satiety, dyspnea (labored breathing), and diarrhea. The median survival for all patients with myelofibrosis is about six years but is considerably worse for intermediate 2- and high-risk patients at 4 years and 2.25 years, respectively. Besides causing disease-related morbidity, myelofibrosis may result in early death from leukemic progression, which can occur in about 20% of patients, and complications arising from progressive bone marrow failure, portal or pulmonary hypertension, infections, clotting, bleeding, and cardiovascular complications.

Myelofibrosis is a relatively rare condition with an incidence of 0.1 to 1 per 100,000 individuals per year, and a prevalence of 6 per 100,000 person-years because of its chronic nature and disabling course. It is estimated that 18,000 patients are living with myelofibrosis in the United States. Median age at diagnosis is 67 years. Myelofibrosis may occur de novo as primary myelofibrosis (PMF) or may arise from a preexisting myeloproliferative neoplasm (MPN), including primarily polycythemia vera (PV) or essential thrombocytosis (ET).

### Importance of Anemia in Myelofibrosis

Anemia is a cardinal feature of myelofibrosis, and RBC transfusion dependence is a hallmark of the late-stage disease. Within a year of diagnosis, 45% of patients with myelofibrosis are already RBC transfusion dependent and eventually nearly all will develop transfusion dependence.

Transfusion dependence is a critical negative prognostic factor for survival for patients with myelofibrosis. Transfusions are associated with both acute and chronic health risks, and they place a significant burden on both the patient and the health care system. Severe anemia and transfusion dependence are independent predictors of poor prognosis and are inversely correlated with quality of life. Conversely, response to anemia-targeted therapies has been associated with improvement in quality of life. The prognostic effect of anemia was recently demonstrated in 1,109 consecutive PMF patients at the Mayo Clinic, 86% of whom presented with some degree

of anemia. Even mild anemia impaired survival, while severe anemia (defined as Hgb level of < 8 g/dL or transfusion dependence) was associated with > 1.5-fold increase in risk of death compared with moderate anemia (Hgb level of 8-10 g/dL).

Existing approaches for the management of myelofibrosis associated anemia include transfusion, erythropoiesis-stimulating agents in patients with low erythropoietin levels, corticosteroids, androgens (including danazol), immunomodulators, and splenectomy. Each of these treatments is described by the National Comprehensive Cancer Network (NCCN) as minimally effective.

### Momelotinib - A Potent and Selective JAK1, JAK2 and ACVR1 Inhibitor

Momelotinib is a potent, selective, small-molecule inhibitor of JAK1, JAK2 and ACVR1, under development for treatment of patients with myelofibrosis. Momelotinib was discovered by Cytopia Research, which commenced an initial Phase 1/2 clinical trial in the United States in 2009. Cytopia was acquired by YM BioSciences, Inc. in 2010, which continued clinical development of the compound, before its own acquisition by Gilead in 2013. Amongst other clinical studies, Gilead conducted two registration-track Phase 3 trials in subjects with myelofibrosis, GS-US-352-0101 (SIMPLIFY-1) and GS-US-352-1214 (SIMPLIFY-2). In August 2018, we acquired the momelotinib program from Gilead and assumed the role of IND sponsor in September 2018 with the intent to continue development of momelotinib for the treatment of myelofibrosis. Several members of our senior management team were previously executives at Cytopia and/or YM BioSciences and led the early development of momelotinib.

Following our acquisition of the program, we conducted a comprehensive review of data from the two Phase 3 trials of momelotinib, versus ruxolitinib (SIMPLIFY-1) and best available therapy (BAT) (SIMPLIFY-2), as well as GS-US-352-1672, a Phase 2, open-label, translational biology trial of momelotinib in transfusion-dependent subjects with myelofibrosis. In aggregate, our analyses across a variety of datasets show consistent benefit in the three cardinal disease manifestations of myelofibrosis across a spectrum of intermediate-high risk patients with myelofibrosis, both JAK inhibitor naïve and previously JAK inhibitor exposed: namely, (1) anemia and transfusion dependency, (2) constitutional symptoms, and (3) enlarged spleen, consistent with the compound's differentiated inhibition of JAK1, JAK2 and ACVR1. Although SIMPLIFY-1 met its primary efficacy endpoint of non-inferior spleen volume reduction, it did not meet its key secondary efficacy endpoint of non-inferior reduction in total symptom score; and although SIMPLIFY-2 did not meet its primary efficacy endpoint of superior reduction in spleen volume, it did meet its key secondary efficacy endpoint of superior reduction in total symptom score. In both SIMPLIFY studies, additional secondary endpoints related to transfusion independence rate, transfusion dependence rate, and rate of red blood cell transfusions all favored momelotinib over control and supported the potential for momelotinib to provide meaningful anemia benefits. As such, we have determined that there is substantial clinical justification for further development of momelotinib.

Among the JAK-inhibitor class, momelotinib uniquely inhibits JAK1, JAK2 and ACVR1. All three targets contribute to disease manifestations of myelofibrosis in complex and overlapping ways. The dominant roles for each in driving the various disease manifestations include: JAK1, abnormal cytokine production and immune dysregulation; JAK2, clonal myeloid proliferation; and ACVR1, anemia. Evidence suggests that momelotinib can provide an array of differentiated and compelling anemia-related clinical benefits, while also providing symptomatic and splenic benefits clinically comparable to the approved standard-of-care, ruxolitinib. Specifically, via inhibition of JAK1 and JAK2, momelotinib is uniquely positioned as the only JAK-inhibitor demonstrated to provide comparable splenic benefit when compared directly to ruxolitinib in the JAK inhibitor treatment-naïve setting, while Phase 3 data strongly suggest the potential for momelotinib to provide substantial symptom benefit for both JAK-inhibitor treatment-naïve and exposed patients with myelofibrosis. In addition, momelotinib induces robust, clinically meaningful and consistent anemia benefits, likely via inhibition of ACVR1 and JAK1, as demonstrated in the two momelotinib Phase 3 trials and in the Phase 2 translational biology trial (GS-US-352-1672) in transfusion-dependent patients.

Myelofibrosis-associated anemia is dependent on a number of factors and involves the hyperactivation of two parallel signal transduction pathways that drive production of the peptide hormone hepcidin. Hepcidin is the master regulator of iron metabolism, and elevated levels in myelofibrosis perturbs iron homeostasis and exacerbates anemia. The principle pathway directing hepcidin expression involves activation of ACVR1, whereas a secondary pathway increases hepcidin in response to inflammation and JAK-STAT signaling. Momelotinib directly inhibits ACVR1, JAK1 and JAK2 to effectively limit hepcidin production. This unique profile induces a dose-dependent decrease in serum hepcidin, restoring iron homeostasis and alleviating anemia.

In a nonclinical anemia model, momelotinib treatment increased circulating plasma iron, RBC production, and Hgb levels consistent with the observed reduction in inflammatory cytokine and hepcidin levels associated with inhibition of JAK1, JAK2 and ACVR1. This effect of momelotinib was further validated by data from trial GS-US-352-1672 in an advanced, transfusion-dependent myelofibrosis population in which 34% and 39% of patients achieved transfusion independence for at least 12 and 8 weeks, respectively. Median plasma hepcidin levels declined acutely after momelotinib dosing and chronically over the entire 24-week dosing period, suggesting momelotinib induced a sustained reduction of both predose (basal) and postdose levels of hepcidin. In an exploratory post-hoc analysis, a substantial reduction in transfusion frequency was also observed in subjects who did not achieve complete transfusion independence.

Similarly, substantially higher rates of transfusion independence and lower rates of transfusion dependency were observed in momelotinib-treated subjects compared with ruxolitinib or BAT-treated subjects in the SIMPLIFY-1 and SIMPLIFY-2 pivotal trials. In an exploratory aggregate analysis including 152 transfusion dependent patients treated with momelotinib across the SIMPLIFY-1, SIMPLIFY-2, and GS-US-352-1672 trials, the combined 8- and 12-week transfusion independence response rates across this continuum of JAK-inhibitor naïve and exposed, intermediate- and high-risk myelofibrosis patients, were 48.7% and 44.1%, respectively. The rate of transfusion independence in transfusion-dependent subjects, along with other anemia benefits, were broadly consistent across these trials, and are consistent with the empirical findings of a pronounced anemia benefit observed in initial Phase 1/2 momelotinib clinical studies.

In addition, there is extensive evidence of momelotinib's sustained positive effects on hemoglobin (Hgb) and other anemia endpoints. A robust and long-lasting increase in Hgb was observed in the GS-US-352-1672 trial, which enrolled only transfusion-dependent subjects. A similar observation was noted in the JAK inhibitor naïve SIMPLIFY-1 trial, where a rapid and sustained increase in Hgb was observed in subjects randomized to momelotinib, which contrasted with the acute and profound reduction in Hgb by treatment with the standard-of-care, ruxolitinib. Notably, subjects who crossed over to momelotinib treatment following 24 weeks of ruxolitinib therapy experienced a rapid and substantive increase in Hgb, ultimately achieving sustained Hgb levels that exceeded those observed in the pretreatment baseline period.

In totality, over 1,200 subjects have been treated with momelotinib across more than 20 clinical studies, with over 820 myelofibrosis patients treated to date. Uniquely among the JAK inhibitor class, this substantive body of clinical data has demonstrated consistent and reproducible therapeutic benefits for momelotinib across all three hallmarks of myelofibrosis, anemia, enlarged spleen and symptoms. In general, momelotinib has proven to be generally well tolerated, with certain patients having received continuous daily dosing of momelotinib for more than 8 years, indicative of momelotinib's potential to provide long-term tolerability and sustained benefit. In the randomized phases of SIMPLIFY 1 and SIMPLIFY 2 the most commonly reported treatment emergent adverse events for subjects treated with momelotinib were thrombocytopenia, diarrhea, headache, asthenia and nausea. The most commonly reported Serious Adverse Events (SAEs) were anemia, atrial fibrillation, diarrhea, pneumonia and cardiac failure. These SAEs include events assessed as both related and unrelated to momelotinib and each occurred in < 4% of subjects.

### Momelotinib - Next Steps

During the fourth quarter of 2019, we launched the MOMENTUM clinical trial for patients with myelofibrosis. The randomized double-blind global Phase 3 trial is designed to confirm the efficacy of momelotinib on

myelofibrosis symptoms, transfusion independence and splenomegaly, as compared to danazol. The trial is targeting enrollment of 180 myelofibrosis patients who are symptomatic, anemic and have been treated previously with a JAK inhibitor. We anticipate reporting top-line data from the trial in late 2021. Data from MOMENTUM, along with data from more than 820 patients previously treated myelofibrosis with momelotinib, will form the basis of the global registration strategy for momelotinib.

### DDR Programs - SRA737 and SRA141

### SRA737, a Potent, Highly Selective, Orally Bioavailable Chk1 Inhibitor

SRA737 is a potent, highly selective, orally bioavailable small molecule inhibitor of Chk1 being investigated in two Phase 1/2 clinical trials that were initiated in the third quarter of 2016 in the United Kingdom under a Clinical Trial Authorization (CTA). SRA737 was licensed to us in September 2016 and in January 2017, we successfully transferred sponsorship of the trials to Sierra.

Checkpoint kinase 1 (Chk1) is a serine-threonine kinase and master regulator of cell cycle progression and the DNA Damage Response (DDR) replication stress response. One of the hallmarks of cancer is genomic instability. A major source of genomic instability in certain tumors arises as a consequence of dysregulated cell cycle checkpoints and aberrant DNA replication, resulting in high replication stress (RS), which is manifested by stalled replication forks and associated DNA damage. Chk1 regulates multiple cell-cycle phases, temporarily inhibiting the progression of cell replication and division in order to ensure proper replication of the genome and repair of collapsed or damaged replication forks. Chk1 stabilizes stalled replication forks, manages origin firing to avoid further replication stress, and mediates DNA repair via homologous recombination in the event of fork collapse. Tumors with high RS become reliant on Chk1 to mitigate the potentially catastrophic consequences of excess genomic instability. As such, Chk1 represents a promising therapeutic target in cancers with high RS, as inhibiting Chk1 drives excessive genomic instability which can result in replication catastrophe and tumor cell death.

During the second quarter of 2019, we reported preliminary efficacy and safety data from these two trials at the 2019 ASCO Annual meeting. We also announced plans to prioritize our resources on the development of momelotinib and that we would be launching a campaign exploring non-dilutive strategic options to support any future continued development of SRA737.

### SRA737-01 Phase 1/2 Monotherapy Trial

This signal-seeking Phase 1/2 study (NCT02797964) was designed to investigate the safety and tolerability of continuous, oral daily dosing of SRA737, as well as to survey a broad range of cancer indications and genetic contexts in the expansion phase, in order to evaluate preliminary anti-tumor activity and delineate potential genetic signatures and/or tumor indications that might warrant additional therapeutic investigation.

At the 2019 ASCO Annual meeting, we reported preliminary efficacy and safety data from this trial. Evidence of anti-tumor activity was observed in subjects with HGSOC, colorectal, prostate and non-small cell lung cancer; no RECIST PRs or CRs were confirmed, but several noteworthy tumor reductions were recorded.

### SRA737-02 Phase 1/2 Low-Dose Gemcitabine Combination Trial

Extensive preclinical data, as well as emerging clinical data, support the synergistic interaction between Chk1 inhibition and gemcitabine. Gemcitabine profoundly depletes DNA replication building blocks, and targets proliferating cells by inducing replication stress through induction of stalled replication forks and double-strand breaks. Low concentrations of gemcitabine cause a prolonged cell cycle S-phase and induce hallmarks of replication stress without inducing overt cytotoxicity. The critical role of Chk1 in mediating cellular responses to replication stress affords the opportunity to combine SRA737 with sub-therapeutic concentrations of the replication stress-inducing agent gemcitabine.

This signal-seeking Phase 1/2 study (NCT02797977) was designed to investigate the safety and tolerability of SRA737 in combination with sub-therapeutic, low dose gemcitabine (LDG), as well as to evaluate preliminary anti-tumor activity of SRA737 potentiated by LDG in tumors with genetic alterations predicted to confer increased intrinsic RS and Chk1i sensitivity. Relative to standard-of-care, gemcitabine doses tested were approximately 10-25% of a standard chemotherapeutic dose.

At the 2019 ASCO Annual meeting, we reported preliminary efficacy and safety data from this trial. Overall, Partial Responses were observed in six subjects and 41 subjects had a best response of Stable Disease (SD); durable SD lasting <sup>3</sup> 4 months was recorded in 32 subjects and was observed in all expansion cohorts. The combination of SRA737+LDG was generally well tolerated.

### SRA141, a Highly Selective, Orally Available Cdc7 Inhibitor

SRA141 is a highly selective, orally available small molecule inhibitor of Cdc7. SRA141 was licensed to us in May 2016 from Carna Biosciences, Inc., Kobe, Japan (Carna).

Cdc7 is a serine-threonine kinase which acts as an essential regulator of both DNA replication and the DDR network. Over-expression of Cdc7 and its partner proteins is correlated with unfavorable clinical outcomes and poor survival in a broad range of solid tumors and hematological malignancies. In preclinical studies, inhibition of Cdc7 has been shown to cause cancer cell death in a p53-independent manner, and to induce tumor stasis or regression in a variety of in vivo cancer models.

Status of Our Preclinical Development Program for SRA141

We reported preclinical data in a late-breaking poster presented in the second quarter of 2019 at the AACR Annual Meeting highlighting a possible mechanism of cytotoxicity for SRA141.

We have successfully completed the IND process with the U.S. Food and Drug Administration (FDA) for SRA141 and have designed a potential Phase 1/2 trial with this drug candidate.

In the second quarter of 2019 we announced that we launched a campaign exploring non-dilutive strategic options to support any future continued development of SRA141.

### **Asset Purchase Agreement**

In August 2018, we entered into an Asset Purchase Agreement with Gilead whereby we acquired worldwide rights to the pharmaceutical product momelotinib, an investigational orally-bioavailable JAK1, JAK2 and ACVR1 inhibitor together with all related intellectual property rights and certain other related assets. Pursuant to the agreement, we made a one-time upfront payment of \$3.0 million in August 2018. In October 2019, we entered into an amendment to the Asset Purchase Agreement in which we agreed to issue, subject to certain conditions, shares of common stock and a warrant to purchase common stock to Gilead in consideration for meaningfully reduced royalty rates and elimination of a near term milestone payment in the Asset Purchase Agreement. Pursuant to the amended agreement, milestone payments of up to an aggregate of \$190.0 million may become payable to Gilead upon the achievement of certain regulatory and commercial milestone events and we are now required to pay Gilead low double-digit to high-teens percent tiered combined royalties based upon net sales. The effectiveness of the amendment and the issuance of the shares of common stock and warrant to Gilead was conditional upon the completion of an offering that closed in November 2019.

### **License Agreements**

### CRT Pioneer Fund LP License Agreement

In September 2016, we entered into an exclusive license agreement with CRT Pioneer Fund LP (CPF) for worldwide rights, know-how and materials to develop SRA737, a small molecule inhibitor targeting Chk1, a

promising therapeutic target to treat cancer. Pursuant to the agreement, we made a one-time upfront payment of \$7.0 million to CPF in October 2016 and paid \$2.0 million to CPF in January 2017 for the successful transfer of two ongoing Phase I clinical trials. Additional milestone payments of up to an aggregate of \$319.5 million may become payable to CPF upon the achievement of certain developmental, regulatory and commercial milestones including milestone payments of \$7.5 and \$12.0 million that would be due to CPF upon the dosing of the first patient in the first Phase 1 trial of SRA737 in the United States and upon the dosing of the first patient of a randomized Phase 2 trial of SRA737, respectively (in the event that the milestone payment for Phase 2 becomes due, but no milestone payment for Phase 1 has been paid, then the milestone payment for Phase 1 will become due and payable contemporaneously with the payment for the Phase 2 milestone for an aggregate payment of \$19.5 million). In addition, we are required to pay CPF, on a product-by-product and country-by-country basis, tiered high single-digit to low double-digit royalties on the net sales of any product successfully developed until the later of (i) the date when such licensed product is no longer covered by a valid patent claim within the licensed intellectual property, (ii) the expiration of any data, marketing or other statutory exclusivity rights covering the licensed product, or (iii) a specified period after the first commercial sale of the licensed product. Such royalties will be reduced on a product-by-product and country-by-country basis under certain conditions, including if certain generic competition exists in such country, or if we are required to pay royalties to third parties in order to develop or commercialize the licensed product.

The license agreement will expire on the date of expiration of our obligation to pay royalties to CPF. Either party may terminate the license agreement if the other party materially breaches the license agreement, subject to certain cure provisions, and CPF may terminate the license agreement in certain limited circumstances as described in the license agreement. The license agreement may also be terminated at any time by us upon 90 days' prior written notice to CPF.

### Carna Biosciences, Inc. License Agreement

In May 2016, we entered into an exclusive license agreement with Carna Biosciences, Inc. (Carna) for worldwide rights to develop and commercialize SRA141, a small molecule kinase inhibitor targeting Cdc7. In exchange for this exclusive right, we paid Carna an upfront payment of \$0.9 million in June 2016. We will be required to pay Carna milestone payments of up to an aggregate of \$270.0 million upon achievement of certain developmental, regulatory and commercial milestone events, including a milestone payment of \$4.0 million upon dosing of the first patient in the first Phase 1 clinical trial for SRA141. In addition, for product candidates defined under the license agreement, we are required to pay Carna on a product-by-product and country-by-country basis, tiered single-digit royalties on net sales.

The license agreement will expire on the date of expiration of our obligation to pay royalties to Carna. Following the expiration of the license agreement, we will obtain a fully paid-up, non-exclusive license to develop and commercialize products relating to the licensed intellectual property worldwide for any use. Carna may terminate the license agreement if we materially breach the agreement, subject to certain cure provisions. The license agreement may also be terminated at any time by us upon 30 days' prior written notice to Carna.

### **Intellectual Property**

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for momelotinib, SRA737, SRA141 and future product candidates, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary or intellectual property rights. Our strategy is to seek to protect our proprietary position and intellectual property position by, among other methods, filing patent applications related to our proprietary technology and product candidates in the United States and in foreign jurisdictions. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

We have acquired all rights to patent portfolios directed to compositions of matter and methods of use related to momelotinib and other JAK 1/2 and ACVR1 inhibitors. As of December 31, 2019, these rights included three

issued U.S. patents comprising claims directed to compositions of momelotinib and methods of using momelotinib for the treatment of myelofibrotic indications as a single agent. Two of these patents will expire in 2028 while the third patent will expire in 2030, absent any extensions. As of December 31, 2019, these rights also include 52 issued foreign patents and one pending foreign patent application in 48 jurisdictions, including Australia, Canada, China, Europe, Japan, Korea, Mexico, Russia and others comprising claims directed to compositions of momelotinib for the treatment of myelofibrotic indications as a single agent. These foreign patents, and any patent issuing from the pending foreign patent application, are expected to expire in 2028, absent any extension. As of December 31, 2019, these rights also included two issued U.S. utility patents and one pending reissue application comprising claims directed to different polymorph and salt forms of momelotinib, and methods of their use for the treatment of myelofibrotic indications. These patents will expire in 2035, absent any extension. Note that for issued U.S. patents, up to five years of patent term extension is available for a single patent directed to the composition of momelotinib, bringing the possible patent exclusivity in the U.S. out to 2040. As of December 31, 2019, these rights also included five issued foreign patents, one allowed European application and 15 pending foreign patent applications in 14 jurisdictions, including Australia, Brazil, Canada, China, Hong-Kong, India, Israel, New Zealand, Mexico, Japan, Korea, Singapore and Taiwan comprising claims directed to different polymorph and salt forms of momelotinib. These foreign patents, and any patent issuing from these pending foreign patent applications, are expected to expire in 2035, absent any extension. Note that for issued European patents, up to five years of term extension is available via a Supplementary Protection Certificate (SPC) for a single patent directed to the composition of momelotinib, bringing the possible patent exclusivity in Europe out to 2040. As of December 31, 2019, these rights also included four issued foreign patents in four jurisdictions, including Australia, New Zealand, Singapore and South Africa comprising claims directed to methods of using momelotinib for the treatment of anemia. As of December 31, 2019, these rights also included one issued U.S. patent comprising claims directed to methods of using momelotinib for the treatment of ACVR1-mediated diseases. This U.S. patent will expire in 2037, absent any extensions. We have filed and will continue to file patent applications directed to the composition of matter and methods of use related to various aspects of momelotinib as they develop.

We have exclusively licensed CPF's rights to patents owned by Cancer Research Technology (CRT), a subsidiary of Cancer Research UK (CRUK), directed to compositions of matter and methods of use related to SRA737 and other Chk1 inhibitors, As of December 31, 2019, these rights included two issued U.S. patents and one pending U.S. patent application comprising claims directed to compositions of SRA737 and methods of using SRA737 for the treatment of cancer indications as a single agent, or in combination with a DNA damaging agent. The two issued U.S. patents and any patents issuing from the pending U.S. utility application are expected to expire in 2033, absent any adjustments or extensions. As of December 31, 2019, these rights also included 26 issued foreign patents and 6 pending foreign patent applications in 27 foreign jurisdictions, including Australia, Canada, China, Europe and Japan comprising claims directed to compositions of SRA737 and methods of using SRA737 for the treatment of cancer indications as a single agent, or in combination with a DNA damaging agent. These foreign patents, and any patents issuing from these pending foreign patent applications, are expected to expire in 2033, absent any extensions. As of December 31, 2019, these rights also included one pending Patent Cooperation Treaty application, one pending U.S. application and 3 pending foreign applications comprising claims directed to biomarkers and patient selection when using SRA737 to treat cancer indications. Any patents issuing from these pending patent applications are expected to expire in 2038, absent any adjustments or extensions. As of December 31, 2019, these rights also included one pending U.S. application and 7 pending foreign applications comprising claims directed to methods of using SRA737 in combination with PARP inhibitors for inhibiting tumor reduction. Additionally, as of December 31, 2019, these rights also included one pending Patent Cooperation Treaty application comprising claims directed to methods of using SRA737 to treat cancer indications. We have filed and will continue to file patent applications directed to the composition of matter and methods of use related to various aspects of SRA737 as they develop.

We have exclusively licensed from Carna rights to patent applications directed to the SRA141 composition of matter, alone or in combination with an M-phase inhibitor, and methods of use for the combination. As of December 31, 2019, we were the exclusive licensee of two U.S. patents and one pending U.S. patent application

comprising composition of matter claims directed to SRA141. These patents, and any patents that issue from the pending U.S. application will expire in 2032, absent any adjustments or extensions. As of December 31, 2019, this exclusively-licensed patent family included 22 issued foreign patents and three pending foreign patent applications in 21 foreign jurisdictions, including Australia, Canada, Europe, India, Japan, Korea and Mexico and others comprising composition of matter claims directed to SRA141. The foreign patents, and any patents issuing from these pending foreign patent applications, are expected to expire in 2032, absent any extensions. Additionally, as of December 31, 2019, the rights also included a pending Patent Cooperation Treaty application comprising claims directed to methods of using SRA141 to treat cancer indications. Any patents issuing from this pending patent application are expected to expire in 2039, absent any adjustments or extensions. We have filed and will continue to file patent applications directed to the composition of matter and methods of use related to various aspects of SRA141 as they develop.

The term of individual patents depends upon the legal term for 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 filed patent. The term of a patent that covers a drug may also be eligible for patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. In the future, if and when our product candidates receive approval by the FDA, the European Medicines Agency (EMA) or other foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those drugs, depending upon the length of the clinical trials for each product candidate and other factors. There can be no assurance that any of our pending patent applications will issue or that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents.

As with other oncology 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, patent applications that we may file or license from third parties may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. Our issued patents and any issued patents that we may receive in the future may be challenged, invalidated or circumvented. For example, we cannot be certain of the priority of inventions covered by pending third-party patent applications. If third parties prepare and file patent applications that also claim technology or therapeutics to which we have rights, we may have to participate in interference proceedings to determine priority of invention, which could result in substantial costs to us, even if the eventual outcome is favorable to us. 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 momelotinib, SRA737, SRA141 or 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 reducing any advantage of any such patent.

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our scientific advisors and consultants, and invention assignment agreements with our employees. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses requiring invention assignment, to grant us ownership of technologies that are developed through our relationship with a third party.

### Competition

The hematology and oncology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. 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. While

we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies that are available for the indication or indications for which they are approved and new therapies that may become available in the future.

To our knowledge, there are currently two approved drugs for the treatment of myelofibrosis that specifically rely on JAK inhibition, ruxolitinib, marketed by Incyte Corporation as Jakafi® in the United States and by Novartis as Jakavi in rest of the world and fedratinib, marketed by Celgene Corporation as Inrebic® in the United States. CTI Biopharma Corporation is developing the JAK inhibitor, pacritinib, which is currently in the early stages of a Phase 3 study. However, to our knowledge, there are no drugs that target both JAK and ACVR1 inhibition on the market, nor in development. Other competitors in the myelofibrosis market include Acceleron and Constellation Pharma. Acceleron is developing luspatercept in a Phase 2 clinical trial for myelofibrosis in conjunction with Celgene. Constellation Pharma is developing CPI-0610, a BET inhibitor with recent corporate disclosure suggesting future directions will include a Phase 3 clinical trial in combination with ruxolitinib. Several additional companies are in the early stages of development in the myelofibrosis market. If momelotinib is approved, it will compete with existing therapies for the indication or indications for which it is approved. While we believe that momelotinib may have the ability to provide an anemia benefit, which we believe is unique to the JAK inhibitor class of agents, the market for momelotinib is competitive, and physicians and other prescribers may not recommend or prescribe momelotinib over other competing products.

To our knowledge, there are no approved drugs that specifically target Chk1 on the market, but there are a number of competitors in clinical development, at a similar stage of development or more advanced than us. To our knowledge, Esperas Pharma is conducting a Phase 1/2 clinical trial of an oral Chk1 inhibitor as monotherapy and in combination with gemcitabine in patients with advanced or metastatic cancer. There are also preclinical programs focused on developing Chk1 inhibitors. If SRA737 is approved, it will compete with existing therapies and currently marketed drugs for the indication or indications for which it is approved.

Additionally, to our knowledge, there are no approved drugs that specifically target Cdc7. To our knowledge, Takeda Pharmaceutical Company is developing an oral Cdc7 inhibitor that is currently in a Phase 2 clinical trial for squamous esophageal and squamous non-small-cell lung cancers and Eli Lilly and Company has a Cdc7 inhibitor program that is currently in a Phase 1 clinical trial being conducted by Cancer Research UK. Other companies may be conducting preclinical studies of Cdc7 inhibitors as well. If SRA141 is approved, it will compete with existing therapies for the indication or indications for which it is approved.

Many of the companies against which we may compete have significantly greater financial and other 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 hematology and oncology 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 that may be necessary for, our programs.

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 drugs that we may develop. Our competitors also may obtain FDA or foreign regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic drugs.

### **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 and supply of preclinical study and clinical trial materials in relation to our lead product candidate, momelotinib, and our other product candidates, including materials for any combination trials that we may undertake, and any future potential product candidates that we may develop for preclinical and clinical testing, as well as for commercial manufacture if our product candidates receive marketing approval.

We do not currently have arrangements in place for redundant supply. We believe that our manufacturers have sufficient capacity to meet our current demand and, in the event that they fail to meet our demand, adequate alternative sources for such materials exist. However, there is a risk that if supplies are interrupted or result in poor yield or quality, it would materially harm our business. We will continue to evaluate product demand requirements and qualify alternate sources for momelotinib, and our other product candidates on an as-needed basis.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, which govern recordkeeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our contract manufacturing organizations are required to comply with current good manufacturing practice (cGMP) regulations, which are regulatory requirements for the production of pharmaceuticals that will be used in humans.

### **Government Regulation**

### **FDA Approval Process**

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, consent decrees, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices (GLPs). The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted (i) in compliance with federal regulations; (ii) in compliance with good clinical practice (GCP), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (IRB) for approval. An IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects and has the authority to approve, require modifications in (to secure approval), or disapprove research. IRB review serves an important role in the protection of the rights and welfare of human research subjects. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy volunteers or patients, the drug is typically tested to assess pharmacokinetics, pharmacodynamics, safety, various doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population (with the targeted disease) to determine the activity of the drug for a particular tissue-specific, or possibly genetically-specific patient population, dosage tolerance and optimum dosage for Phase 3 studies, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to confirm clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 or Phase 2 trial with other confirmatory evidence may be sufficient in certain instances, such as where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the applicant under an approved NDA is also subject to an annual program fee for each prescription drug product, which replaced the annual product and establishment fees. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug products are reviewed within ten to twelve months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for drugs intended to treat a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices (cGMPs) is satisfactory and the NDA contains data that provide evidence that the drug is safe and effective in the indication studied.

After FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require Risk Evaluation and Mitigation Strategies (REMS) to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for REMS can materially affect the potential market and profitability of the drug, and typically require substantial documentation and communication with the FDA. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

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

### FDA Regulation of Companion Diagnostics

If an in vitro diagnostic is essential to the safe and effective use of a therapeutic product, then the FDA generally will require approval or clearance of the diagnostic at the same time that FDA approves the therapeutic product. The FDA has generally required in vitro companion diagnostics intended to select the patients who will respond to cancer treatment to obtain a pre-market approval, or PMA, for that diagnostic simultaneously with approval of the drug. The review of these in vitro companion diagnostics in conjunction with the review of our cancer treatments involves coordination of review by the FDA's Center for Drug Evaluation and Research and by the FDA's Center for Devices and Radiological Health.

The PMA process, including the gathering of clinical and nonclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to a substantial application fee, which is typically increased annually. In addition, PMAs for devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic

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

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay or prevent approval. If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

### **Pediatric Information**

Under the Pediatric Research Equity Act (PREA), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA generally does not apply to a drug for an indication for which orphan designation has been granted; however, beginning in 2020, PREA will apply to NDAs for orphan-designated drugs if the drug is molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that FDA has determined is substantially relevant to the growth or progression of a pediatric cancer. The Best Pharmaceuticals for Children Act (BPCA) provides NDA holders a six-month extension of any exclusivity—patent or non-patent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

### Fast Track Designation and Accelerated Approval

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment, and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the drug candidate. FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. Under the fast track program and FDA's accelerated approval regulations, FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a

surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by FDA.

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with FDA, FDA may initiate review of sections of a fast track drug's NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, the fast track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

### Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly-available information to gain knowledge regarding the progress of development programs.

#### **Post-Approval Requirements**

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

AE reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

#### The Hatch-Waxman Act

### Orange Book Listing

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

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

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

### Exclusivity

Upon NDA approval of a new chemical entity (NCE), which is a drug that contains no active moiety that has been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which FDA cannot approval an ANDA for a generic drug that includes the change. An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.

### Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent term extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval). The time can be shortened if FDA determines that the applicant did not pursue testing and review with due

diligence. The total patent term after the extension may not exceed 14 years from NDA approval. For patents that might expire during the review phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The Director of the United States Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted. Up to five years of patent term extension is potentially available for a single US issued patent directed to the momelotinib composition of matter upon NDA approval. We have acquired patent rights including two issued U.S. utility patents and one pending reissue application comprising claims directed to a polymorph and salt form of momelotinib. These patents will expire in 2035, absent any extension. If five years of patent term extension is applied to one of these patents, the patent exclusivity for momelotinib in the U.S. would extend to either 2040 or the maximum allowable 14-year limit from NDA approval, whichever is sooner.

### Anti-Kickback, False Claims Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain general business and marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes, false claims statutes and other statutes pertaining to healthcare fraud and abuse. The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act (PPACA) amended the intent element of the federal statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws, including the federal civil False Claims Act, prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, PPACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal False Claims Act. The majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the Health Insurance Portability

and Accountability Act of 1996, or HIPAA, which prohibits knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

### Other Federal and State Regulatory Requirements

Manufacturers of prescription drugs are required to collect and report information on certain payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members. The reports must be submitted on an annual basis and the reported data are posted in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties. Effective January 1, 2022, reporting on transfers of value to physician assistants, nurse practitioners or clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives will also be required.

In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the posting of information relating to clinical studies and their outcomes. Some states require the reporting of certain pricing information, including information pertaining to and justifying price increases, or prohibit prescription drug price gouging. In addition, states such as California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Additional jurisdictions, such as the City of Chicago and the District of Columbia, require pharmaceutical sales representatives to be licensed and meet continuing education requirements. Several additional states are considering similar proposals. Compliance with these laws is difficult and time-consuming, and companies that do not comply with these state laws face civil penalties.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act (HITECH), and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, imposes specified requirements on certain types of people and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, 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 attorney's fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, contractual damages, reputation harm, and diminished profits or future earnings, any of which could adversely affect our ability to operate our business and our financial results.

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

### Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. Sales of pharmaceutical products depend significantly on the availability of third-party coverage and reimbursement. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. Although we currently believe that third-party payors will provide coverage and reimbursement for our product candidates, if approved, these third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of our products. The product candidates that we develop may not be considered cost-effective. It is time-consuming and expensive for us to seek coverage and reimbursement from third-party payors. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

The marketability of any product candidates for which we or our collaborators receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

### Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

By way of example, in March 2010, the PPACA was signed into law, which intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the PPACA of importance to our potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures, or imports specified branded prescription drugs and biologic agents,
   apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- 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;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D. (The Bipartisan Budget Act of 2018 increased the manufacturers subsidy under this program from 50% to 70% beginning in 2019);

- extension of a manufacturer's Medicaid rebate liability to cover drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- · expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been judicial and Congressional challenges and amendments to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future, including the potential repeal of all or part of PPACA. In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, which will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

### Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country and may require us to perform additional pre-clinical or clinical testing.

### Approval in the European Union

In the European Union, Member States require both regulatory clearances by the national competent authority and a favorable ethics committee opinion prior to the commencement of a clinical trial. Under the European Union regulatory systems, marketing authorization applications may be submitted under either a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union Member States. We would be subject to the centralized process. Under the centralized procedure, pharmaceutical companies submit a single marketing authorization application to the EMA. Once granted by the European Commission, a centralized marketing authorization is valid in all European Union Member States, as well as the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway. By law, a company can only start to market a medicine once it has received a marketing authorization.

### European Regulation of Clinical Trials and Grant of Marketing Authorization

Pharmaceutical products in the European Union are subject to regulation under comprehensive legislation enacted by the European Commission in the European Medicines Directive 2001/83/EC, as amended. This directive is binding on all Member States together with ancillary legislation governing research.

### Clinical Trial Authorization

Clinical trials are regulated under European Council Directive 2001/20/EC (Clinical Trials Directive) on the implementation of GCP in the conduct of clinical trials of medicinal products for human use. The Clinical Trials Directive requires the sponsor of an investigational medicinal product to obtain a CTA, much like an IND in the United States, from the national competent authority of a European Union Member State in which the clinical trial is to be conducted. The application for CTA must satisfy detailed requirements for the protection of trial subjects including requirements relating to consent and specific rules for minors and adults unable to consent by reason of incapacity. The CTA application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the Council Directive and corresponding national laws of the Member States and further detailed in applicable guidance, including the European Commission Communication 2010/C 82/01. A clinical trial may only be commenced after an Ethics Committee has given its approval. It is uncertain whether the United Kingdom will still be subject to the European Council Directive 2001/20/EC (Clinical Trials Directive) in the future. In particular it is not yet known definitively whether the United Kingdom will follow the European pathway for the regulation of clinical trials commenced after the United Kingdom's exit from the European Union (Brexit) on January 31, 2020. The government of the United Kingdom and the MHRA have not yet published whether United Kingdom clinical trial applications regarding new medicinal products will continue to be authorized by MHRA and ethics committees as they are presently.

A sponsor of a clinical trial must also follow certain procedures, including entering specified relevant information in the European trial database, EudraCT. In addition, Member States require that the manufacture and/or importation of investigational medicinal products be authorized. Sponsors of investigational medicinal products must ensure compliance with, among other things, GCP and good manufacturing practice (GMP) as well as requirements pertaining to safety reporting.

In April 2014, Regulation EU No 536/2014 (Clinical Trials Regulation) was adopted to replace the Clinical Trials Directive. The Clinical Trials Regulation is intended to simplify the current rules for clinical trial authorization and standards of performance. For instance, there will be a streamlined application procedure via a single-entry point, a European Union portal and database. The implementation of the Clinical Trials Regulation has been delayed until late 2020. In December 2019, the EMA management board endorsed the decision to commence the audit of the clinical trial information system (CTIS) in December 2020. The new clinical trial portal and database will be maintained by the EMA in collaboration with the European Commission and the European Union Member States. The objectives of the new Regulation include consistent rules for conducting trials throughout the European Union, consistent data standards and adverse events listing, and consistent information on the authorization status. Additionally, information on the conduct and results of each clinical trial carried out in the European Union will be made publicly available.

### Procedural Routes for Marketing Authorization

The European system for authorization of medicinal products for human use offers several routes: the centralized procedure, the decentralized procedure, and the mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union Member States as well as the EEA countries of Iceland, Liechtenstein and Norway. The centralized procedure is mandatory for certain categories of investigational products, including human products containing a new active substance indicated for the treatment of certain diseases, including cancer, AIDS, diabetes and neurodegenerative illness; orphan medicinal products; and medicinal products manufactured using biotechnological processes. Applications

for marketing authorization for such medicines must be submitted to the EMA, in which the Committee for Medicinal Products for Human Use (CHMP) is generally responsible for conducting the initial assessment of a product.

The decentralized and mutual recognition procedures are applicable to the majority of conventional medicinal products and are both based on the principle of recognition of a marketing authorization by one or more Member States. The decentralized procedure is available for applicants who wish to market a product in various European Union Member States where such product has not received marketing approval in any European Union Member State before. In this procedure, an application for marketing authorization is submitted simultaneously in several Member States, one of them being chosen as the "Reference Member State." At the end of the procedure, national marketing authorizations are granted in the Reference and in the concerned Member States. The mutual recognition procedure is used when a medicinal product has already received a marketing authorization in one Member State and is compulsory to be marketed in a Member State other than that in which they were first authorized. Any national marketing authorization granted by a European Union Member State's national authority can be used to support an application for its mutual recognition by other Member States.

### Standard for Approval of a Marketing Authorization

The objective of the EMA is the comprehensive evaluation of benefit/risk profile of a new medicinal product going through the centralized procedure. This evaluation involves showing that the product has significant efficacy and safety, together with a satisfactory plan for risk management post-marketing. The CHMP is the EMA's expert committee responsible for human medicinal products. The CHMP is responsible for conducting the initial review of European Union-wide marketing authorization applications and for assessing modifications or extensions (variations) to an existing marketing authorization. It also considers the recommendations of the Pharmacovigilance Risk Assessment Committee on the safety of medicines on the market and when necessary, recommends to the European Commission changes to a medicine's marketing authorization, or its suspension or withdrawal from the market. The marketing authorization application is similar to the NDA in the United States. All application procedures require an application in the common technical document (CTD), which includes the submission of detailed information about the manufacturing and quality of the product, and non-clinical and clinical trial information. The main scientific principle used by the CHMP in the evaluation of medicinal products is the benefit/risk ratio based on quality, efficacy, safety, and risk management considerations. The CHMP assesses whether the data it reviews comply with the ICH-harmonized Good Practices published for GCP, GMP and good laboratory practice (GLP). The CHMP also considers whether studies concluding efficacy and safety of products have sufficient statistical power.

When the United Kingdom leaves the European Union, the United Kingdom will no longer automatically comply with the standards of clinical efficacy, safety and chemistry control, and manufacture as applied by the European Medicines Directive. Applications submitted for marketing authorization under the centralized EMA procedure will no longer be automatically validated for authorization in the United Kingdom and the benefit-risk assessments conducted by the United Kingdom may not be consistent with the EMA conclusions.

### Other Regulatory Issues

An exemption to the rule requiring marketing authorization permits Member States of the European Union to make a product available for compassionate use to patients with a chronically or seriously debilitating disease or whose disease is considered life threatening, such as cancer, and who cannot be treated satisfactorily by an authorized medicinal product. The medicinal product concerned must be undergoing clinical trials or the subject of application for marketing authorization.

Quality of the medicinal products in question is governed by the GMP Directive. This lays down the principles and guidelines of GMP for both marketed medicinal products and investigational products in clinical trials. The Directive obliges manufacturers to comply with GMP for an effective pharmaceutical quality assurance, quality

control, systems for recording and reviewing complaints and a system for prompt recall of products in the distribution network. With regards to post—marketing safety of newly authorized products, the EMA is responsible for coordinating the Member States' ongoing evaluation of benefit risk, supervision and pharmacovigilance of medicinal products.

The pharmacovigilance legislation imposes a duty on Member States to collect information on the risks of products with regards to patients' or public health. That information must refer to adverse events arising from the use of the medicinal product within the terms of the marketing authorization as well as use outside the authorized indication and use associated with occupational exposure.

There is a similar obligation on the marketing authorization holder (MAH) to operate a robust pharmacovigilance system equivalent to that of the relevant Member State. The MAH must evaluate all safety and effectiveness information scientifically, consider the options for risk minimization and take appropriate measures as necessary. As part of the pharmacovigilance system, the MAH must have permanently and continuously an appropriately qualified person responsible for pharmacovigilance, maintain a pharmacovigilance master file, operate a risk management system for each medicinal product, monitor the outcome of risk minimization measures contained in the risk management program and continually update the risk management system and monitor the pharmacovigilance system to determine whether there are new risks or changes to the risk-benefit profile of the product(s).

Two recent developments have been introduced which further expand the European regulatory framework: the Falsified Medicines Directive and the Pharmacovigilance Directive. The Falsified Medicines Directive obliges manufacturers of medicinal products to audit their suppliers of active substances to ensure compliance with GMP. It also introduces a new obligation on product manufacturers to inform the competent authority (e.g., MHRA) and the marketing authorization holder if they become aware that these products may be falsified, whether they are being distributed through the legitimate supply chain or by illegal means. The Pharmacovigilance Directive obliges marketing authorization holders to monitor the safety of authorized products and detect any change in their risk-benefit profile. A new pan-European clinical trial data information database has been created that will be complementary to the database established for pharmacovigilance (Regulation (EC) No 726/2004 with respect to European Union authorized medicinal products). In addition, Commission Implementing Regulation (EU) No 520/2012 outlines the practical implications for marketing authorization holders, national competent authorities, and the EMA. Also, Commission Delegated Regulation (EU) No 357/2014 on post-authorization efficacy studies specifies the situations in which such studies may be required. Post-authorization efficacy studies may be required where concerns relating to some aspects of efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed, or where the understanding of the disease, the clinical methodology or the use of the medicinal product under real-life conditions indicate that previous efficacy evaluations might have to be revised significantly. Brexit will disrupt the operation of pre- and post-authorization clinical trial infrastructure.

The United Kingdom enacted the Data Protection Act 2018 to directly enforce the General Data Protection Regulation (GDPR). The government of the United Kingdom has stated that the United Kingdom will still abide by the provisions of the GDPR after Brexit. However, in the event of a "no deal" Brexit it is uncertain whether this commitment will still be met. In the case of a "no deal" Brexit, it is also uncertain whether clinical trial data and pharmacovigilance adverse event data originating from the United Kingdom will be compliant with European Union privacy legislation and whether the data will be incorporated by EMA in the assessment of the ongoing benefit-risk profile and hence continued support of European Union marketing authorizations. The government of the United Kingdom has issued guidance as to how data protection will work in the event of a "no deal" Brexit. The European Union (Withdrawal) Act 2018 will ensure that the fundamental principles, obligations, and rights of GDPR that apply to organizations and data subjects will stay the same after Brexit. New regulations will preserve European Union GDPR standards in domestic law and will:

 Transitionally recognize all EEA countries (including European Union Member States) and Gibraltar as adequate to allow data transfers from the United Kingdom to Europe to continue;

- Preserve the effect of existing European Union adequacy decisions on a transitional basis;
- Recognize European Union Standard Contractual Clauses (SCCs) in United Kingdom law and give the ICO the power to issue new clauses:
- Recognize Binding Corporate Rules (BCRs) authorised before Exit day;
- Maintain the extraterritorial scope of the United Kingdom data protection framework; and
- Oblige non-United Kingdom controllers who are subject to the United Kingdom data protection framework to appoint representatives in the United Kingdom if they are processing United Kingdom data on a large scale.

As of January 2021, the European Union regulatory framework described above may no longer apply to the United Kingdom. It is unclear whether the United Kingdom will continue to be a full member of the European Union. The United Kingdom formally left the European Union on January 31, 2020 and has entered into a transition arrangement until a comprehensive trade agreement between the United Kingdom and European Union is negotiated by year-end 2020. It is not yet certain, if the European Union regulatory framework for medicinal products and medical devices will continue to govern the relevant law in the United Kingdom during this transition.

The government of the United Kingdom has also issued guidance on the regulation of medical devices (including companion diagnostics) in the event of a no-deal Brexit. The primary European Union directives regarding active implantable medical devices and in vitro medical devices will be transposed into European Union in the Medical Devices Regulations (2002), Consumer Rights Act, the Consumer Protection and the General Product Safety Regulations. Additionally, two new European Union Regulations entered into force on May 25, 2017: Regulation 2017/745, the European Union Medical Devices Regulation; and Regulation 2017/746, the European Union IVMDR. The following will apply to the United Kingdom in that all the key elements contained therein will be brought into line with the transitional timetable being followed by the European Union for the full application of those two regulations.

- The MHRA will continue to perform market surveillance of medical devices on the United Kingdom market and will have decision
  authority over the marketing and supplying of a device in the United Kingdom, regardless of the position of the European regulatory
  network, or any post-exit decision of the European Court of Justice.
- Manufacturers wishing to place a device on the United Kingdom market will have to register with MHRA or designate a suitable person to register and act on its behalf. They will also have to comply with the following additional responsibilities:
  - correctly classifying the device against the new risk classification criteria;
  - meeting general safety and performance requirements, including for labelling and technical documentation and quality management systems;
  - meeting increased requirements for clinical evidence;
  - having a person responsible for regulatory compliance in place; and
  - · meeting the new vigilance reporting timescales and creating an annual periodic safety update report.

### Approval Outside the United States/European Union

For marketing outside the United States and the European Union, we are subject to foreign regulatory requirements governing human clinical testing and marketing approval for our products. Whether or not FDA or European Commission approval has been obtained for a product, approval of the product by comparable

regulatory authorities of countries outside of the United States or the European Union, as the case may be, must be obtained prior to marketing the product in those countries. Approval in one country does not assure that a product will be approved in another country. In certain countries, regulatory requirements and approval processes are similar to those in the United States and the European Union, where approval decisions by regulators are based on the regulators' review of the results of clinical trials performed for specific indications. Other countries may have a less comprehensive review process in terms of data requirements and may rely on prior marketing approval from a foreign regulatory authority in other countries such as the United States or the European Union. In many countries outside of the United States, approvals for pricing, coverage and reimbursement offered by third-party payers, including government payers and private insurance plans, are also required.

### **Employees**

As of December 31, 2019, we had 71 employees, of which 15 had M.D. or Ph.D. degrees and 48 were engaged in research and development activities. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

### **Corporate Information**

We were incorporated in Delaware in May 2003 as Phenome Systems, Inc. and changed our name to ProNAi Therapeutics, Inc. in April 2004. Shortly thereafter, we merged with SenseGene Therapeutics Inc., a Michigan corporation, with ProNAi Therapeutics, Inc. being the surviving corporation. We changed our name to Sierra Oncology, Inc. in January 2017. Our principal executive offices are located at 2150 – 885 West Georgia Street, Vancouver, British Columbia, Canada V6C 3E8, and our telephone number is (604) 558-6536. Our website address is www.sierraoncology.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report, and you should not consider information on our website to be part of this Annual Report.

### **Available Information**

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other information with the Securities and Exchange Commission (SEC). Our filings with the SEC are available free of charge on the SEC's website at *www.sec.gov* and on our website under the "Investors" tab as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

### 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 report, 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. The occurrence of any of the events or developments described below could harm 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.

### **Risks Related to Our Business and Industry**

We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses for the foreseeable future.

We are a clinical stage hematology and oncology company with a limited operating history. Since inception, we have incurred significant operating losses. Our net losses were \$88.3 million, \$53.3 and \$42.0 million for the year ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated

deficit of \$765.7 million. Investment in hematology and oncology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. For example, in June 2016 we decided to suspend the development of our former lead product candidate PNT2258 after an interim analysis of data from a Phase 2 clinical trial of PNT2258 indicated only modest efficacy. We have no products approved for commercial sale and have not generated any revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue the development of our lead product candidate, momelotinib, fund research and preclinical studies and clinical trials, seek to identify additional product candidates, in-license additional products or technologies, seek regulatory approval, prepare for potential commercialization which will require a significant investment in areas related to contract manufacturing and inventory buildup and continue to operate as a public company.

Even if we succeed in commercializing momelotinib, or any future product candidates we may acquire or develop, we will continue to incur substantial research and development and other expenditures to develop and market these and other product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our business is highly dependent on the success of our lead product candidate, momelotinib. If we are unable to successfully develop, obtain regulatory approval for and commercialize momelotinib, or experience significant delays in doing so, our business will be materially harmed.

Our business and future success depends on our ability to successfully develop, obtain regulatory approval for and commercialize momelotinib. While momelotinib is a late-stage product candidate for which previous Phase 3 clinical trial data suggest the potential to provide promising safety and efficacy in patients who are JAK inhibitor naïve and in patients who have an inadequate response to, progression on or are intolerant of ruxolitinib, it will require additional clinical testing, including at least one additional adequate and well-controlled Phase 3 clinical trial, before we can seek regulatory approval and begin commercialization, if it all. While the FDA has provided regulatory clarity concerning the design of our Phase 3 clinical trial for momelotinib, and even though we launched our MOMENTUM Phase 3 clinical trial for momelotinib in the fourth quarter of 2019, there is no guarantee that we will obtain regulatory approval and be able to begin commercialization. Before we can generate any revenue from sales of momelotinib, we must complete additional development activities, including, for our preclinical product candidates, submit Investigational New Drug Applications (INDs) and/or Clinical Trial Authorizations (CTAs) or foreign equivalents of either, and for any of our product candidates, marketing applications such as New Drug Applications (NDAs) or foreign equivalents, for regulatory review and approval in multiple jurisdictions, make substantial investments, obtain access to sufficient commercial manufacturing capacity and engage in significant marketing and commercial access efforts.

We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product candidates from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from similar regulatory authorities outside of the United States, such as the EMA in Europe and the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom. Applications for regulatory approval and regulatory approval of our product candidates could be delayed or be denied for many reasons, including but not limited to the following:

- the FDA or foreign regulatory authorities may disagree with the number, design or implementation of our clinical trials;
- the population studied in the clinical trial may not be considered sufficiently broad or representative to assure safety in the full population for which we seek approval;

- the FDA or 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 meet the level of statistical or clinical significance required by the FDA or foreign regulatory authorities or may otherwise not be sufficient to support the submission of an NDA, marketing authorization application or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the FDA or foreign regulatory authorities may require us to conduct additional preclinical studies and clinical trials;
- we may be unable to demonstrate to the FDA or foreign regulatory authorities that our product candidate's response rate, duration of response or risk-benefit ratio for its proposed indication is acceptable;
- the FDA or foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications applicable to the manufacture of our product candidates, the facilities of third-party manufacturers with which we contract for clinical and commercial supplies may fail to maintain a compliance status acceptable to the FDA or foreign regulatory authorities or foreign regulatory authorities may fail to approve facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- we or any third-party service providers may be unable to demonstrate compliance with current good manufacturing practices (cGMPs) and/or good clinical practices (GCPs) to the satisfaction of the FDA or foreign regulatory authorities, which could result in delays in regulatory approval;
- the regulations or policies of the FDA or foreign regulatory authorities may change in a manner rendering our clinical data insufficient for approval; or
- political factors surrounding the approval process, such as government shutdowns and political instability.

Even if momelotinib or another product candidate were to be approved by the FDA or foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for momelotinib or any other product candidate in one or more jurisdictions, or if any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development, marketing or commercialization of momelotinib or any other product candidate. If competitive products developed by third parties show significant benefit in the indications in which we are developing our product candidates, any planned supportive or primary registration trials may be delayed, altered, terminated or not initiated and our other product candidates may never receive regulatory approval. Our clinical development programs for our product candidates may also not receive regulatory approval if we have inadequate financial or other resources to advance these product candidates through the clinical trial process. Furthermore, even if we obtain regulatory approval for any of our product candidates, we will still need to develop sales, marketing and commercialization infrastructure, or collaborate with a third party for the commercialization of our product candidates, establish commercially viable pricing and obtain approval for coverage and adequate reimbursement from third parties, including government payors. If we are unable to successfully commercialize any of our product candidates, we may not be able to generate sufficient revenues to continue our business.

If we are unable to successfully develop and commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We will be required to demonstrate through clinical trials, to the satisfaction of regulatory authorities, that our product candidates are safe and effective for use in their target indications before we can obtain regulatory approval for their marketing and commercial sale.

We previously acquired from Gilead our lead product candidate momelotinib, a potent, selective and orally-bioavailable JAK1, JAK2 and ACVR1 inhibitor. Momelotinib has been investigated in two completed Phase 3 trials for the treatment of myelofibrosis, and we launched our MOMENTUM Phase 3 clinical trial for momelotinib, in the fourth quarter of 2019 after receiving regulatory feedback concerning the design of the trial. We cannot guarantee that the regulators will agree with us regarding the data we believe will be sufficient to support submission and approval of a marketing application for momelotinib. To the extent we cannot secure agreement from the FDA or the EMA on such data, there may be an increased risk of delay in obtaining approval or of obtaining approval at all.

We reported preliminary efficacy and safety data for SRA737 at the 2019 ASCO Annual Meeting in June 2019, suggesting that this product candidate may have anti-cancer activity in certain cancer indications. For SRA141, we have identified a potentially novel mechanism of cytotoxicity and our IND is now in effect, enabling the commencement of clinical trials. To support the continued development of SRA737 and SRA141 in the future, we intend to seek non-dilutive strategic options. There can be no assurance that we will successfully obtain non-dilutive development support or obtain the funding or support necessary to advance SRA737 or SRA141 or obtain such funding or support on commercially reasonable terms. If we are unable to obtain such funding or support, we may need to cease development of these product candidates. Additionally, upon the dosing of the first patient in the first Phase 1 trial of SRA737 in the United States, under the current terms of our license agreement with CRT Pioneer Fund LP (CPF), we would owe CPF a milestone payment of \$7.5 million, and upon the dosing of the first patient of a randomized Phase 2 trial of SRA737, we would owe CPF a milestone payment of \$12.0 million. In the event that the milestone payment for Phase 2 becomes due, but no milestone payment for Phase 1 was paid, then the milestone payment for Phase 1 will become due and payable contemporaneously with the payment for the Phase 2 milestone for an aggregate payment of \$19.5 million. If we are unable to renegotiate these milestone payments or raise additional capital, our ability to continue developing SRA737 may be adversely affected.

The success of our product candidates and any future product candidates that we may acquire or develop will depend on many factors, including, but not limited to, the following:

- ability to obtain funding or secure non-dilutive strategic development resources to support development costs;
- successful completion of preclinical studies;
- successful translation of preclinical results in human clinical trials;
- successful enrollment in, and completion of, clinical trials that produce data which adequately demonstrate the product candidate's benefit
  and risk profile;
- successful transfer of existing trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishment of clinical trial material and commercial manufacturing capabilities, or arrangements with third-party manufacturers and suppliers on commercially reasonable terms;
- effective patent and trade secret protection and regulatory exclusivity;
- establishment of a commercial sales team, if and when approved, whether alone or in collaboration with others;
- acceptance, if and when approved, by patients, the medical community and third-party payors;
- coverage and adequate reimbursement by third-party payors, including government payors;
- successful competition with other therapies;
- continued acceptable safety profile following approval;

- enforcement and protection of intellectual property rights and claims;
- · achievement of desirable medicinal properties for the intended indications; and
- effective growth of an organization of scientists and businesspeople who can develop and commercialize our products, if approved, and technology.

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 develop and commercialize our product candidates, including our lead product candidate, momelotinib, which would materially harm our business.

If further preclinical development or clinical trials of our lead product candidate, momelotinib, or any other current or future product candidates that we may develop or acquire fail to demonstrate acceptable safety and efficacy or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of current or future product candidates.

Before obtaining marketing approval from regulatory authorities, including the FDA, for the sale of our product candidates, we must complete preclinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later preclinical testing and clinical trials, and interim results of a clinical trial do not necessarily predict final results. Many companies in the biotechnology industry have suffered significant setbacks in later-stage clinical trials after achieving positive results in early-stage development, and there is a high failure rate for product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. For example, in June 2016, we announced that we decided to suspend the development of our former lead product candidate PNT2258 after an interim analysis of data from a Phase 2 clinical trial of PNT2258 indicated only modest efficacy. We cannot guarantee that we will be successful in obtaining the required efficacy and safety profile from our lead product candidate momelotinib, or any other current or future product candidate. A failure of one or more preclinical studies or clinical trials can occur at any stage of testing.

We previously acquired from Gilead our lead product candidate momelotinib, a potent, selective and orally-bioavailable JAK1, JAK2 and ACVR1 inhibitor. Momelotinib has been investigated in two completed Phase 3 trials for the treatment of myelofibrosis, SIMPLIFY-1 and SIMPLIFY-2. Based on the results of the prespecified analyses, neither trial was considered sufficiently compelling to justify the submission of an application for regulatory approval. Although SIMPLIFY-1 met its primary efficacy endpoint of non-inferior spleen volume reduction, it did not meet its key secondary efficacy endpoint of non-inferior reduction in total symptom score; and although SIMPLIFY-2 did not meet its primary efficacy endpoint of superior reduction in total symptom score. In both SIMPLIFY studies, additional secondary endpoints related to transfusion independence rate, transfusion dependence rate, and rate of red blood cell transfusions all favored momelotinib over control and supported the potential for momelotinib to provide meaningful anemia benefits. Based on post hoc analyses of the data for these trials that we subsequently conducted, we believe the trials showed promising substantive spleen and constitutional symptom control. In addition, we believe momelotinib has the potential to provide a differentiated therapeutic profile encompassing anemia-related benefits. As such, we have determined that there is substantial clinical justification for further development of momelotinib.

The FDA previously provided regulatory feedback concerning the design of our MOMENTUM Phase 3 clinical trial for momelotinib, that we launched in the fourth quarter of 2019. While we believe the safety and efficacy profile of momelotinib in patients who have an inadequate response to, progress on, or are intolerant of ruxolitinib appears promising based on the prior Phase 3 trial results, the MOMENTUM Phase 3 trial we recently

commenced in those patients may not be successful. This could occur for a variety of reasons related to efficacy or safety outcomes observed in the trial or to issues related to study conduct or study feasibility, including, but not limited to the following:

- failure to identify sufficient countries willing to import and sites equipped to handle the active comparator danazol, a controlled substance in some countries;
- delays in initiation and execution of the study in certain countries due to momelotinib and/or controlled substance danazol shipping and distribution logistical challenges;
- failure to enroll or retain sufficient numbers of subjects because of competing studies, complexity of study design and/or the potential for
  patients to be randomized to a danazol-comparator arm;
- delays in initiation of the trial due to implementation of privacy and data protection legislation;
- issues with data retention due to lack of adherence to privacy and data protection legislation;
- delays in study initiation due to the collection of the primary endpoint data via patient reported outcomes on an electronic device, which requires questionnaire licensing, language translation and programming to support the global study;
- failure to collect sufficient primary endpoint data for the study given its source of patient reported outcomes, including due to patients not accurately or consistently reporting their primary endpoint data or the device itself experiencing technical issues that result in inadequate primary data collection;
- failure to demonstrate sufficiently improved efficacy over the comparator arm of danazol either because momelotinib's efficacy in the trial is less robust than expected or because danazol performs better than expected, given danazol's limited data availability, on the efficacy endpoints; The SIMPLIFY-1 Phase 3 trial, for example, conducted by Gilead in ruxolitinib-naive patients did not demonstrate non-inferiority to its comparator arm of ruxolitinib for the key secondary endpoint of total symptom score; and
- failure to observe meaningful anemia benefits in our planned Phase 3 trial, which could reduce the potential future value of momelotinib as we believe an anemia benefit could potentially provide a competitive advantage over existing therapies.

Additionally, the results of MOMENTUM could be altered, or the trial results could be difficult to interpret, if there is inadvertent unblinding of the treatment assignment of subjects prior to the subject being evaluable for the primary efficacy endpoint or if too many subjects drop out of the study or discontinue the randomized study treatment prior to the subject being evaluable for the primary endpoint. Although danazol, the comparator selected for use in this trial, is not approved for the treatment of myelofibrosis, it is recommended by myelofibrosis guidelines as a treatment option for myelofibrosis associated anemia. Danazol's ability to control myelofibrosis disease manifestations may not be sufficient, and thus subjects randomized to the danazol arm may experience symptomatic deterioration which may increase the risk of inadvertent unblinding, early study discontinuation and/or early discontinuation of randomized treatment. Similarly, momelotinib may also not sufficiently control myelofibrosis disease manifestations in all subjects randomized to the momelotinib arm, and thus subjects in either treatment arm may also be at risk for early discontinuation.

In addition, prior to NDA submission we will need to reach agreement with the FDA regarding pediatric development plans for momelotinib. Under the RACE for Children Act (2017), novel products targeting JAK-1, JAK-2, or ACVR-1 require an agreed Pediatric Study Plan in an oncology indication. The scope of such an agreed plan is currently unknown, but it could include agreement on the conduct of non-clinical and/or clinical studies. In the European Union, we have recently obtained a waiver for pediatric development of momelotinib in myelofibrosis from the Pediatric Committee (PDCO).

We are currently conducting two Phase 1/2 clinical trials of SRA737, which we believe will further inform future clinical development plans and patient selection strategies. We believe we have completed all necessary

preclinical activities to support a potential future IND submission for SRA737 to the FDA. However, we have not yet discussed our plans for any IND submission with the FDA, and if pursued, the FDA may provide feedback that delays the submission or clearance of any IND. While we previously announced positive preclinical data for SRA737 as well as positive preliminary clinical data, we have no assurance that clinical trials of SRA737 will demonstrate safety and efficacy or produce positive results sufficient to justify further development and commercialization.

SRA141 has never been evaluated in a clinical trial. We submitted an IND for SRA141 to the FDA, and the IND is in effect. We have prepared for a Phase 1/2 trial with this product candidate in patients with advanced cancer.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and even if the trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. 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 products. To the extent that the results of our studies and trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

We may experience numerous unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including, but not limited to:

- undesirable side effects or other unexpected characteristics of our product candidates, causing us or our investigators, regulators or IRBs to suspend or terminate the trials;
- regulators or IRBs may not authorize us or our investigators to initiate a clinical trial, conduct a clinical trial at a prospective trial site, or amend a clinical trial;
- · government or regulatory delays and changes in regulatory requirements, policy and guidelines;
- delays in reaching or failure to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites
  and contract research organizations (CROs), or failure by such CROs or trials sites to carry out the clinical trial in accordance with the
  terms of our agreements with them;
- negative or inconclusive results of preclinical studies or clinical trials;
- decision by us to conduct additional preclinical studies or clinical trials or abandon product development programs;
- a higher number of patients being required for clinical trials, slower than expected enrollment, greater than expected competition for patients or higher than expected drop out rates;
- clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment;
- failure of third-party contractors to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- inability or unwillingness of patients or medical investigators to follow our clinical trial protocols;
- suspension or termination of clinical trials for various reasons, including unacceptable health risks;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or site by the FDA or foreign regulatory authorities;
- greater than expected cost of clinical trials;

- insufficient supply or quality of product candidates or other materials necessary to conduct clinical trials;
- delays or additional costs as a result of the United Kingdom's decision to leave the European Union and resulting need to decouple the United Kingdom's regulatory system from that of the European Union; and
- revision of legal or regulatory requirements for approving our product candidates.

If we are required to conduct additional preclinical studies or clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete preclinical studies and clinical trials of our product candidates or other testing, or if the results of these studies, trials or tests do not reflect an acceptable safety or efficacy profile, we may:

- be delayed or unable to submit an IND in the United States, or additional CTAs or equivalents in other countries;
- not have the permission of the FDA or other health authorities to commence clinical trials, or may have a clinical hold placed on one or more of our clinical trials;
- be delayed in obtaining marketing approval;
- not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any preclinical studies or clinical trials will continue as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical studies and clinical trial delays also could allow our competitors to bring products to market before we do and could impair our ability to successfully commercialize our product candidates, any of which may harm our business and results of operations.

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

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The Phase 3 MOMENTUM trial may be especially difficult to enroll because the trial is blinded and because the comparator arm does not contain a JAK inhibitor. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including, but not limited to:

- the number and size of clinical trials for other product candidates in the same therapeutic area that are currently in clinical development, and our ability to compete with such trials for patients and clinical trial sites;
- the patient eligibility criteria defined in the protocols;
- the size of the specific patient populations such as those whose tumors harbor the applicable genetic mutations, if required or other defined subsets of a larger patient population;

- the risk that disease progression will result in death or clinical deterioration before the patient can enroll in clinical trials or before sufficient data has been collected such that the patient contributes no meaningful information for the clinical trial in which the patient is enrolled;
- the proximity and availability of clinical trial sites for prospective patients;
- the design of the trials, including the inclusion of a placebo or comparator arm in a trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Our clinical trials compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates. This competition reduces the number and types of patients and qualified clinical investigators available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors or clinical trial sites may not allow us to conduct our clinical trial at such site if competing trials are already being conducted there. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. We may also encounter difficulties finding a clinical trial site at which to conduct our trials. Moreover, because our product candidates are experimental, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, radiation and other approved therapies, rather than enroll patients in any one of our clinical trials. Global epidemics, such as the coronavirus, could also negatively affect site activation, as well as recruitment and retention, at sites in a region or city whose health care system becomes overwhelmed due to the illness.

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

### We may need to acquire additional capital to complete the development and commercialization of our product candidates.

We may spend substantial capital to advance our current product candidates, including our lead product candidate momelotinib, in preclinical and clinical development, seek regulatory approvals for our product candidates, establish a commercial sales force to market and manufacture products, if any, that are approved for commercial sale. We also incur significant additional compliance and administrative costs as a result of operating as a public company.

Our future capital requirements will depend on many factors, including, but not limited to:

- the progress and results of our MOMENTUM Phase 3 trial and our other planned preclinical studies and clinical trials;
- the scope, progress, results and costs of product candidate discovery, preclinical development, laboratory testing and clinical trials for our future product candidates;
- the costs, timing and outcome of regulatory review of momelotinib and any other product candidates;
- the costs of medical affairs and pre-commercialization activities, including regulatory and reimbursement analysis and market research;
- the costs 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;

- the extent to which we acquire or in-license other drugs and technologies, or to which we out-license our own products and technologies;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- decisions regarding the future development of SRA737 and SRA141;
- the success of any collaborations that we may enter into with third parties;
- the timing and amount of milestone and royalty payments;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive
  marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Identifying potential product candidates and 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 and achieve drug sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of our product candidates, if approved, which we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital, other than our outstanding warrants, and it may be more difficult to raise the amount of capital needed to support planned development of our product candidates. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. In particular, we do not have sufficient funds on hand to adequately prepare for future momelotinib commercialization, if approved. Unless we are able to secure non-dilutive strategic options to support any future continued development of SRA737 and SRA141, we may need to delay or discontinue the development of such product candidates. We could also be required to seek collaborators for our product candidates, at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to such product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. We also may be unable to acquire additional promising product candidates.

Our preclinical and initial clinical development for SRA737 is focused on the development of targeted therapeutics for genetically-defined cancers, which is a rapidly evolving area of science, and the approach we are taking to develop drugs may not lead to marketable products. Genetically-based patient selection strategies might also be employed in future SRA141 development programs.

The discovery and development of targeted therapeutics for genetically-defined cancers, including patients whose tumors harbor the applicable genetic alterations that we believe contribute to cancer, is an emerging field, and the scientific discoveries that form the basis for our efforts to develop genetically-selected product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Additionally, we may consider approaches such as a basket study in which enrollment is focused on a compilation of different tumor types that share a similar genetic signature. We cannot be sure that regulatory authorities, including the FDA and the EMA, will accept our trial designs or that we will be able to obtain approval for our product candidates.

We have initially tested our SRA737 product candidate in certain genetically-defined subpopulations of the general treated cancer population, and we have enrolled selected patients into our Monotherapy and Low-Dose

Gemcitabine combination studies of SRA737, based on genetic alterations in their tumors or other factors such as histology. Future development may or may not require a genetically-based patient selection strategy but in order to obtain marketing approval for SRA737 in the treatment of genetically-defined tumors and cancers, we will need to, among other things, demonstrate to the satisfaction of regulatory authorities that those genetic alterations have predictive clinical utility. We have applied our genetic selection criteria to patients in our Monotherapy and our Low-Dose Gemcitabine combination clinical trials, and our approach may change based on our evolving knowledge of the field and on data obtained in our preclinical research and ongoing clinical trials. The goal of our genetic screening is to enroll patients who we believe have the highest probability of responding to the product candidate in order to show compelling evidence of clinical efficacy. Successful identification of patients is dependent on several factors, including, potentially, achieving certainty as to how specific genetic alterations respond to our product candidates and developing companion diagnostics to identify such genetic alterations as appropriate. For example, although we believe, based on scientific and medical literature, preclinical research, and clinical development, that we have identified certain types and combinations of genetic alterations hypothesized to confer sensitivity to Chk1 inhibition that may be predictive of response to SRA737, we have only recently assessed activity of SRA737 in humans and have not discussed the validity of our genetic selection criteria with regulatory authorities, including MHRA, FDA or EMA. In addition, genetically-based patient selection strategies may also be employed in our SRA141 development programs. If so, the development of SRA141 may also be subject to the risks and uncertainties discussed above.

Our genetic selection strategy for SRA737 used a novel algorithm and is not yet validated as predictive of clinical utility. In addition, patient populations in our trials may not be large enough to allow us to successfully determine efficacy of our product candidates, commercialize our product candidates, and achieve profitability. Regulatory authorities may require we conduct additional clinical trials specific to given tumor types.

In order to obtain marketing approval for SRA737 in patients with genetic alterations hypothesized to confer sensitivity to Chk1 inhibition, if a genetically-based patient selection strategy is pursued, we or a third party advancing development will need to, among other things, demonstrate to the satisfaction of regulatory authorities that those genetic alterations have predictive clinical utility. It may be difficult for us or the third party to demonstrate the predictive clinical utility of our genetic selection criteria, which select for patients that have various combinations of genetic alterations across multiple gene panels. Although regulatory authorities, including FDA, have approved therapies for use in conjunction with companion diagnostic tests that aid in selecting patients for treatment based on genetic markers, to our knowledge neither the FDA nor the EMA has granted marketing approval for a therapy that requires the use of a companion diagnostic that uses broad gene panel testing to select for patients with various combinations of genetic alterations. The scientific evidence to support the feasibility of developing product candidates based on our selection criteria is both preliminary and limited. We have not discussed the validity of our genetic selection criteria with regulatory authorities, and we cannot be sure that regulatory authorities, including the FDA and EMA, will accept our or a third-party's genetic selection criteria.

Furthermore, we cannot be certain that the patient populations in the trials will be large enough to allow us to successfully determine efficacy of our product candidates, commercialize our product candidates, and achieve profitability. If we or a third party is unable to enroll sufficient numbers of patients whose tumors harbor the applicable genetic alterations, or if the product fails to work as we expect, or if we or a third party is unable to demonstrate the predictive clinical utility of our genetic selection criteria, the ability to assess and demonstrate the therapeutic effect of our product candidates could be compromised, resulting in longer development times, larger trials, and a greater likelihood of not obtaining regulatory approval for our product candidates. In addition, regulatory authorities may require that our product candidates be studied in clinical trials specific to given tumor (i.e., tissue) types, which may increase the time and costs required. Even if our product candidates demonstrate efficacy in a particular tumor type, we cannot guarantee that any product candidate will behave similarly in multiple or all tumor types, and we or a third party may be required to obtain separate regulatory approvals for

each tumor type we intend a product candidate to treat. We do not know if our approach will be successful, and if our approach is unsuccessful, our business may suffer.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics for SRA737 and our other product candidates could harm our or a third party's drug development strategy and operational results.

In any pivotal clinical trials of SRA737 we anticipate the potential requirement to screen and identify patients with specific genetic alterations who may derive meaningful benefit, as we have begun to do in our Monotherapy and Low-Dose Gemcitabine combination studies of SRA737. To achieve this, if a genetically-based patient selection strategy is pursued by us or a third party, any product development programs for SRA737 and marketing approvals will be dependent on the development and commercialization of a companion diagnostic by us or by third party collaborators. It is feasible that a companion diagnostic might also be required for SRA141 and other potential development programs.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable regulatory authorities, and, to date, the FDA has generally required premarket approval of companion diagnostics for cancer therapies. Generally, when a companion diagnostic is essential to the safe and effective use of a therapeutic product, the FDA requires that the companion diagnostic be approved before or concurrent with approval of the therapeutic product and before a product can be commercialized. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect.

If FDA or a comparable regulatory authority requires approval of a companion diagnostic for any of our product candidates, whether before or after the product candidate obtains marketing approval, we, and/or third-party collaborators, may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of our related product candidates.

We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all.

We have acquired or licensed our product candidates from third parties that had already conducted or were in the process of conducting preclinical studies or clinical trials with our product candidates. We may discover that development efforts of third parties, including but not limited to historical studies and trials conducted by third parties, did not comply with all applicable rules and regulations, and we may experience difficulties or delays in assuming responsibility for or completing such ongoing or previously completed clinical development activities. Our acquisition of momelotinib has resulted in us being required to take over responsibility for conducting ongoing momelotinib trials. Further development and commercialization of momelotinib will require significant financial and operational resources from us.

Prior to our acquisition of momelotinib, our lead product candidate, and licensing of SRA737, third parties had been responsible for all development activities for such product candidates, including, depending on the product, drug process, preclinical and clinical development activities, submission of CTAs and INDs, development of the trial protocols, establishment and management of clinical and safety databases, submission of a pediatric investigation plan (PIP), and other activities. Although we believe the historical development activities were conducted in accordance with applicable rules and regulations in material respects, we cannot assure you that we will not discover inaccuracies or noncompliance in prior development activities that have an adverse effect on the future development of momelotinib or any other of our product candidates. For example, a regulatory authority

may choose to inspect an investigational site and/or vendor such as a CRO for a momelotinib study that was previously conducted by Gilead such as the SIMPLIFY-1 or SIMPLIFY-2 studies. Findings from such inspections could have an impact on the review of any future marketing applications by the FDA or foreign regulatory authorities.

In connection with our acquisition of momelotinib, we have assumed the responsibility for ongoing clinical studies with momelotinib, including related expenses and manufacturing and regulatory activities, which were previously managed and funded by Gilead. This includes responsibility for the ongoing extended access study, which provides extended access of momelotinib to certain patients previously enrolled in Gilead-sponsored studies, who are currently receiving treatment with momelotinib and have not experienced progression of disease. Further, extended access programs provide supportive safety information for regulatory review. Any adverse events or reactions experienced by subjects in the extended access program may be attributed to momelotinib and may limit our ability to obtain regulatory approval with labeling that we consider desirable, or at all.

From time to time we may amend the clinical protocols for our product candidates to include additional objectives that could yield important scientific information critical to our overall development strategy. The protocol amendment process requires review and approval by several review bodies, including regulatory agencies and scientific, regulatory and ethics boards. These protocol amendments may not be accepted by the review bodies in the form submitted, or at all, which may delay our planned enhancements to the clinical development program and/or limit or change the type of information we may gather from those studies.

While regulatory feedback was obtained concerning the design of our Phase 3 clinical trial for momelotinib from both the US and EU regulatory authorities, additional regulatory, scientific, ethics committee, and possibly other reviews will be required during the activation process for the MOMENTUM Phase 3 trial before the protocol is active at any particular site. It is possible that these reviews could require changes to the design of the study. If the MHRA, FDA, EMA, an ethics committee or scientific review board, or another regulatory authority objects to or otherwise does not accept or approve any future protocols or protocol amendments or requires us to further modify trial protocols, our related planned clinical development program may be delayed or suspended and/or we may not be able to gather information we think would be useful to advance development of our lead product candidate, momelotinib, or other product candidates, and our development programs may be adversely affected.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. In November 2019 we conducted a public equity offering where we raised net proceeds of approximately \$97.7 million in a substantially dilutive transaction to our pre-existing investors. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be further diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us.

We may expend our limited resources to pursue a particular product candidate, such as our lead product candidate momelotinib, and fail to capitalize on product candidates that may later prove to be more profitable or for which there is a greater likelihood of success. In addition, we may intentionally halt or terminate programs in order to conserve capital and focus on our remaining program or programs, which may increase our reliance on those programs to be successful.

Because we have limited financial and managerial resources, we focus our research and development efforts on certain selected product candidates, such as our lead product candidate momelotinib. As a result, we may advertently or inadvertently forgo or delay pursuit of opportunities with other product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. In addition, if we halt or terminate programs in order to conserve capital and focus on our remaining program or programs, it may increase our reliance on the success of such programs and raise our exposure to the risk of failure among any of our programs.

The manufacture of our lead product candidate, momelotinib, and our other product candidates requires outsourced, custom manufacturing and we may encounter difficulties in production, particularly with respect to formulation, process development or scaling up of our manufacturing capabilities. If our third-party manufacturers or suppliers encounter such difficulties, our ability to provide supply of our product candidates for preclinical studies, clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

As product candidates are developed, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned preclinical studies or future clinical trials.

Currently, momelotinib is manufactured using an optimized drug substance process by third-party manufacturers, and SRA737 and SRA141 are manufactured using unoptimized processes by third-party manufacturers.

Supply chain logistics are complex for the MOMENTUM Phase 3 clinical trial of momelotinib, as it requires the administration of both an active drug (momelotinib) and an active comparator (danazol) and there are risks associated with this process throughout the supply chain, from labeling, to distribution, dispensing, and administration. Although we have secured sufficient quantities of drug substance and drug product to supply our current momelotinib program, starting with the MOMENTUM Phase 3 clinical trial of momelotinib, we will need to obtain additional supplies from third-party manufacturers that we have engaged, or expect to engage. We have also secured sufficient quantities of danazol drug product to supply the comparator for the initial subjects who will enroll in the study. However, additional sourcing of danazol will be necessary in the future in order to complete the MOMENTUM Phase 3 clinical trial. Thus, we will need to obtain additional supplies from third-party manufacturers that we have engaged or expect to engage. Given the seemingly reduced use of danazol globally, demands for supply have decreased and therefore the ability to secure the required supply could be challenging and potentially impact the ability to execute and complete MOMENTUM. In addition, we may need to develop a pediatric formulation for momelotinib in the future. Although we are working to develop commercially viable manufacturing processes, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale up or formulation, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials.

Any of these challenges could delay completion of preclinical studies or clinical trials, require bridging studies or trials, or the repetition of one or more studies or trials, increase development costs, delay approval of our product

candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our reliance on third-party manufacturing partners or suppliers may cause our supply of research and development, preclinical and clinical development materials to become limited or interrupted or fail to be of satisfactory quantity or quality.

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture and supply of preclinical study and clinical trial materials in relation to our lead product candidate, momelotinib, and our other product candidates, including materials for any combination trials that we may undertake, and any future potential product candidates that we may develop for preclinical and clinical testing, as well as for commercial manufacture if our product candidates receive marketing approval. We have engaged, or expect to engage, third-party manufacturers to obtain materials and consumables necessary for the manufacture of momelotinib and our other product candidates.

We may be unable to establish further agreements with third-party manufacturers and suppliers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers and suppliers entails additional risks, including, but not limited to:

- reliance on the third party for sufficient quantity and quality;
- the possible breach of the manufacturing or supply agreement by the third party;
- failure to manufacture or supply the product according to our specifications;
- failure to manufacture or supply the product according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how;
- · the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance and safety reporting.

While we require our third-party manufacturers and suppliers to comply with cGMPs in the manufacture of clinical trial materials and commercial supply, should we obtain approval of any product candidates, these third-party manufacturers and suppliers may cease to continue to comply with cGMPs—which are FDA requirements for ensuring product quality control—or similar regulatory requirements outside the United States. Our contract manufacturers and suppliers are subject to continual review and periodic inspections to assess compliance with cGMPs. Accordingly, although we are not involved in the day-to-day operations of our contract manufacturers or suppliers, we are ultimately responsible for ensuring that our products and product candidates, and any other materials that may be used in our preclinical or clinical studies or trials, are manufactured or supplied in accordance with cGMPs. Therefore, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, quality control and quality assurance. Our failure, or the failure of our third-party manufacturers or suppliers, to comply with applicable regulations could result in our product candidates not being approved or sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or approved products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business and results of operations.

Additionally, our third-party manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, or unstable political environments, or medical epidemics such as the coronavirus outbreak. For example, many of our raw materials for manufacture of momelotinib are produced in China which could impact our ability to manufacture and supply material for clinical and commercial supply. If

our contract manufacturers were to encounter any manufacturing difficulties or delays due to these factors, our ability to provide our product candidates to patients in clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

Any performance failure on the part of our existing or future manufacturers or suppliers, any interruption or poor yield or quality of manufactured or supplied materials, or any interruption or delay caused by a third party being subject to governmental regulations or moratoriums could result in additional costs, not having sufficient quantities or sufficient quality and may delay, prevent or impair our development, commercialization or marketing efforts. We do not currently have arrangements in place for redundant supply. If any one of our current contract manufacturers or suppliers cannot perform as agreed, we may be required to replace that manufacturer or supplier. Although we believe that there are several potential alternative manufacturers or suppliers who could manufacture or supply our product candidates or the materials for trials relating to product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

If our third-party manufacturers or suppliers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers or suppliers. Our manufacturers and suppliers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Thus, our current and anticipated future dependence upon others for the manufacture or supply of our product candidates or related medicines and materials may adversely affect our development timeline, our future profit margins or our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

Our product candidates may cause undesirable side effects or have other properties that could halt their development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

It is possible that the FDA or foreign regulatory authorities may not agree with any assessment of the safety profile of our product candidates. Undesirable side effects caused by any of our product candidates could cause us, IRBs, our CROs, the FDA or foreign regulatory authorities to interrupt, delay or discontinue development and could result in a clinical hold on any clinical trial, or the denial of regulatory approval by the FDA or foreign regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing our product candidates and generating revenues from their sale. In addition, if any of our products cause serious or unexpected side effects or are associated with other safety risks after receiving marketing approval, a number of potential significant negative consequences could result, including, but not limited to:

- regulatory authorities may withdraw their approval of this product;
- we may be required to recall the product, change the way it is administered, conduct additional clinical trials or change the labeling of the product;
- the product may be rendered less competitive and sales may decrease;

- our reputation may suffer generally both among clinicians and patients;
- we may be exposed to potential lawsuits and associated legal expenses, including costs of resolving claims;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for
  use, or impose restrictions on distribution in the form of a Risk Evaluation and Mitigation Strategy (REMS) in connection with approval, if
  any;
- · we may be required to change the way the product is administered or conduct additional preclinical studies or clinical trials; or
- we may be required to change or stop other ongoing clinical studies that may negatively impact the development of the agent for other indications.

If preliminary data demonstrate that any of our product candidates has an unfavorable safety profile and is unlikely to receive regulatory approval or be successfully commercialized, we may voluntarily suspend or terminate future development of such product candidate.

Any one or a combination of these events could prevent us from obtaining approval and achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

We do not have our own laboratory facilities. We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We do not have our own laboratory facilities. We depend upon independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners to conduct our preclinical studies and clinical trials. We expect to have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs and GLPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for clinical and non-clinical research intended to support a submission or application to FDA or the comparable foreign authority. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable requirements, the data generated in our studies and trials may be deemed unreliable and the FDA or foreign regulatory authorities may require us to perform additional studies or trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our studies or trials comply with the GCP or GLP requirements. In addition, our studies and trials must be conducted with drug product produced under cGMPs. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat studies or trials, which would delay the regulatory approval process. Moreover, ou

Any third parties conducting our preclinical studies and clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their

performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our studies and trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive, or the trials are not well-designed.

Regulatory agencies, IRBs or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. Clinical trials must be conducted in accordance with GCPs, or other applicable foreign regulatory authority guidelines. Clinical trials are subject to oversight by the FDA, foreign regulatory authorities and IRBs at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable cGMPs. Clinical trial data may be rejected by the FDA or foreign regulatory authorities or clinical trials may be suspended by the FDA, foreign regulatory authorities, or us for various reasons, including, but not limited to:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols or to obtain or maintain clinical trial data in accordance with applicable regulatory requirements;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- deficiencies in the trial designs necessary to demonstrate efficacy;
- fatalities or other adverse events (AEs) arising during a clinical trial due to medical problems that may or may not be related to clinical trial treatments;
- the product candidates may not appear to be more effective than current therapies;
- the quality or stability of the product candidates may fall below acceptable standards; or
- failure to adequately demonstrate study conduct oversight, ensure data integrity, and that clinical study sites complied with the principles
  of GCPs.

Although we have never been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial, if we elect or are forced to suspend or terminate a clinical trial of any of our current or future product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. For example, in June 2016 we decided to suspend the development of our former lead product candidate PNT2258 after an interim analysis of data from a Phase 2 clinical trial on PNT2258 indicated only modest efficacy. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners.

# Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our products.

Even if we obtain regulatory approval for our lead product candidate, momelotinib, or one of our other product candidates, they may not gain market acceptance among physicians, patients, healthcare payors and/or the

medical community. We believe that the degree of market acceptance will depend on a number of factors, including, but not limited to:

- timing of market introduction of our product candidates and competitive products;
- safety and efficacy of our products;
- prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- strength of marketing and distribution support;
- price of our products, both in absolute terms and relative to alternative treatments;
- · availability of coverage and reimbursement from government and other third-party payors; and
- sequencing of available products.

If our product candidates are approved for commercial sale and fail to achieve market acceptance, we may not be able to generate significant revenue or achieve or sustain profitability.

We may be subject to requests for access to our product candidates. Demand for compassionate use of our unapproved therapies could strain our resources, delay our drug development activities, negatively impact our regulatory approval or commercial activities, and result in losses.

We are developing product candidates, including our lead product candidate, momelotinib, to treat life-threatening illnesses for which there are currently limited therapeutic options. Other companies in our field have been the target of campaigns requesting access to unapproved drugs. If we experience similar request for access campaigns, we may experience significant disruption to our business which could result in losses. We are a small company with limited resources, and any unanticipated trials or access programs resulting from requests for access could deplete our drug supply, increase our capital expenditures, reduce the availability of potentially eligible clinical trial participants, and otherwise divert our resources from our primary goals.

In addition, legislation referred to as "Right to Try" laws have been introduced at the local and national levels, which are intended to give patients access to unapproved therapies. New and emerging legislation regarding expanded access to unapproved drugs for life-threatening illnesses could negatively impact our business in the future. Either activism or legislation related to requests for access may require us to initiate an unanticipated expanded access program or to make our product candidates more widely available sooner than anticipated.

Patients who receive access to unapproved drugs through compassionate use or expanded access programs have life-threatening illnesses and generally have exhausted all other available therapies. The risk for serious adverse events, including those which may be unrelated to our product candidates, in this patient population is high and could have a negative impact on the safety profile of our product candidate, which could cause significant delays or an inability to successfully commercialize our product candidate and could materially harm our business. In addition, in order to perform the controlled clinical trials required for regulatory approval and successful commercialization of our product candidates, we may receive adverse publicity or experience other disruptions if we do not provide compassionate use access or expanded access programs in response to requests for access from patients in the US or elsewhere in the world. Should we agree to provide compassionate use access or decide to initiate an expanded access program, we could experience adverse publicity or other disruptions related to current or potential participants in such programs. Similarly, we could experience adverse publicity or other disruptions if we were to restructure or pause any compassionate use and/or expanded access program after initiating such a program or after the provision of our product through compassionate access to an individual patient or patients.

We do not have our own laboratory facilities or the ability to discover product candidates. We rely on licensing, acquisition and other forms of strategic relationship to grow our pipeline. Our efforts to acquire additional product candidates and grow our pipeline may be unsuccessful.

We do not have our own laboratory facilities or the ability to discover product candidates. We rely on licensing, acquisition and other forms of strategic relationship to grow our pipeline. We may acquire, or enter into strategic relationships to identify, license and develop, one or more additional product candidates to grow our pipeline. In addition, we may desire to renegotiate our currently existing licensing agreements for any of our product candidates. The identification, evaluation, development and potential acquisition or licensing of additional product candidates or the potential renegotiation of any currently existing licensing agreement for any of our product candidates is expensive and time-consuming, and our efforts may not lead to the acquisition or licensing of any additional product candidates, or successful renegotiation of any currently existing licensing agreement for any of our product candidates, that can be successfully developed and commercialized. Competition for viable product candidates is intense, and the acquisition or licensing of product candidates may be more expensive than we are able to afford or may require us to seek additional financing. If our efforts do not lead to the acquisition or successful identification, development and licensing of suitable product candidates, we may be unable to grow our pipeline. In addition, if our efforts to grow our pipeline require us to pursue additional dilutive capital or debt financing strategies, we may experience harm to our financial position and stability.

Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development. For example, they may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our approach, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

# We face significant competition from other hematology and oncology companies, and our operating results will suffer if we fail to compete effectively.

The hematology and oncology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We may face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies that are available for the indication or indications for which they are approved and new therapies that may become available in the future.

To our knowledge, there are currently two approved myelofibrosis drugs that specifically rely on JAK inhibition, ruxolitinib, marketed by Incyte Corporation as Jakafi® in the United States and by Novartis as Jakavi in rest of the world and fedratinib, marketed by Celgene Corporation as Inrebic® in the United States. In addition, there is one additional JAK inhibitor competitor in clinical development, at a similar state of development or more advanced than us. CTI Biopharma Corporation is developing pacritinib, for myelofibrosis patients with platelet counts less than 50,000/uL and has recently announced enrollment for their Phase 3 PACIFICA study. However, to our knowledge, there are no drugs that target both JAK and ACVR1 inhibition on the market, nor in development. Other competitors developing myelofibrosis therapeutics include Acceleron and Constellation Pharma. Acceleron is developing luspatercept in a Phase 2 clinical trial for myelofibrosis in conjunction with Celgene. Constellation Pharma is developing CPI-0610, a BET inhibitor with recent corporate disclosure suggesting future directions will include a Phase 3 clinical trial in combination with ruxolitinib. Several additional companies are advancing assets in the early stages of development potentially for the myelofibrosis market. If momelotinib is approved, it will compete with existing therapies for the indication or indications for which it is approved. While we believe that momelotinib may have the ability to provide an anemia benefit in addition to treating the other manifestations of myelofibrosis, which we believe is unique within the JAK

inhibition class of agents, the market for momelotinib is competitive, and physicians and other prescribers may not recommend or prescribe momelotinib over other competing products.

To our knowledge, there are no approved drugs that specifically target Chk1 on the market but there are a number of competitors in clinical development, at a similar state of development or more advanced than us. To our knowledge, Esperas Pharma is conducting a Phase 1/2 clinical trial of an oral Chk1 inhibitor as monotherapy and in combination with gemcitabine in patients with advanced or metastatic cancer. There are also preclinical programs focused on developing Chk1 inhibitors. If SRA737 is approved, it will compete with existing therapies for the indication or indications for which it is approved.

Additionally, to our knowledge, there are no approved drugs that specifically target Cdc7. To our knowledge, Takeda Pharmaceutical Company is developing an oral Cdc7 inhibitor that is currently in a Phase 2 clinical trial for squamous esophageal and squamous non-small-cell lung cancers, and Eli Lily and Company has a Cdc7 inhibitor program that is currently in a Phase 1 clinical trial being conducted by CRUK. Other companies may be conducting preclinical studies of Cdc7 inhibitors as well. If SRA141 is approved, it will compete with existing therapies for the indication or indications for which it is approved.

Many of the companies against which we may compete have significantly greater financial and other 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 hematology and oncology 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 that may be necessary for, our programs. Development efforts and clinical results of other companies may be unsuccessful or terminated, which could result in a negative perception of our product candidates, decreases in our stock price and adverse regulatory impacts, which could have a material and adverse effect on our ongoing development programs and our business. For example, in the second quarter of 2019, Eli Lilly and Company removed prexasertib, an intravenous Chk1/Chk2 inhibitor, from its development pipeline.

Our commercial opportunity could be reduced or eliminated if any 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 drugs that we may develop. Our competitors also may obtain FDA or foreign regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors who may place restrictions on patient access to our drugs in seeking to encourage the use of generic or cheaper drugs. If we fail to complete effectively, our business and operating results would be harmed.

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

Our ability to compete in the highly competitive oncology industry depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are dependent on our management, scientific and medical personnel, including Nick Glover, Ph.D., our President and Chief Executive Officer, Barbara Klencke, M.D., our Chief Development Officer and Mark Kowalski M.D., Ph.D., our Chief Medical Officer. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business.

Our operations are conducted in regions where significant competition exists for key personnel and employees. Many other oncology companies and academic and research institutions are located in these regions. Competition

for skilled personnel in these markets is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees.

Should momelotinib receive marketing approval in the United States, Canada, or elsewhere in the world, we would need to hire a substantial number of specialized personnel, including field-based personnel, unless we were to collaborate with a third party to commercialize momelotinib. If we are responsible for commercializing momelotinib, we would need to increase our administrative headcount to support such expanded development and commercialization operations with respect to our product candidates. Our ability to attract and retain qualified personnel in the future is subject to intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses and our current financial position. The loss of the services of any of our senior management could delay or prevent the development and commercialization of our product candidates or have other adverse effects on our business for an indefinite term. In particular, if we lose any members of our current senior management team, we may not be able to find suitable replacements in a timely fashion, if at all, and our business may be harmed as a result.

#### We may encounter difficulties in managing our expected growth and in expanding our operations successfully.

Prior to acquiring momelotinib, our most advanced product candidate was in Phase 1/2 development. Advancing our lead product candidate, momelotinib, through Phase 3 development, will require us to develop or expand our development, regulatory, manufacturing, medical affairs, marketing and sales capabilities or contract with third parties to provide these capabilities for us. We must also successfully integrate the employees and operations related to the development of momelotinib. Maintaining additional relationships and managing our future growth will impose significant added responsibilities on members of our management. We must be able to manage our development efforts effectively, manage our clinical trials effectively, hire, train and integrate additional management, development, medical affairs, administrative and sales and marketing personnel, improve our managerial, development, operational and finance systems, and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure. Our future financial performance will depend, in part, on our ability to manage this growth effectively. We may not be able to accomplish these tasks; which failure could prevent us from successfully developing our product candidates.

We may form or seek strategic alliances, licensing arrangements or other collaborations in the future. We may be unable to form or enter into such alliances or arrangements, and we may not realize the expected benefits of any such transaction.

We may form or seek strategic alliances or licensing arrangements, or create joint ventures or collaborations with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may acquire or develop. Any of these transactions and relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, disrupt our management and business, forego potential future economic value or result in the loss of strategic value. These transactions and relationships also may result in a delay in the development of our product candidates if we become dependent

upon the other party and such other party does not prioritize the development of our product candidates relative to its other development activities.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates, including our lead product candidate, momelotinib, because our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that would justify such transaction.

# Past and future acquisitions could disrupt our business and harm our financial condition and operating results.

We may acquire additional businesses or product candidates from third parties that we believe will complement or augment our existing pipeline of product candidates, including, for example our acquisition of momelotinib from Gilead. Even if the assets we acquire have promising markets or technologies, we may not be able to realize the benefit of acquiring such assets 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 product candidates resulting from an acquisition, including momelotinib, which may 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 or benefits from the asset to justify the transaction. The risks we face in connection with acquisitions, including our acquisition of momelotinib, include, but are not limited to:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- integration of research and development efforts;
- · hiring or training of key employees with knowledge regarding the acquired asset;
- changes in relationships with strategic partners as a result of product acquisitions or strategic positioning resulting from the acquisition;
- cultural challenges associated with integrating employees, knowledge and processes related to the acquired asset into our organization;
- unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired asset.

Our failure to address these risks or other problems encountered in connection with acquisitions could cause us to fail to realize the anticipated benefits of these transactions, cause us to incur unanticipated liabilities and harm the business generally. There is also a risk that future acquisitions will result in the incurrence of debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or operating results.

If we are unable to adequately prepare the market for the potential future commercialization of a product, we may not be able to generate product revenue once marketing authorization is obtained. We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We have not yet begun to prepare for potential future commercialization, and currently have limited commercialization expertise, including no sales, marketing or distribution capabilities and no experience in

marketing products. Advancing momelotinib through Phase 3 development and closer to potential approval will require us to begin commercialization preparation activities and incur related expenses before we obtain final trial results and know whether MOMENTUM will support regulatory approval. These activities will include, among other things, the development of an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other companies to recruit, hire, train and retain qualified marketing and sales personnel. If we are unable to adequately prepare the market for the potential future commercialization of a product, we may not be able to generate product revenue once marketing authorization is obtained.

Additionally, if we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements on commercially reasonable terms, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

We cannot guarantee that we will be able to develop in-house commercialization expertise, including sales and distribution capabilities, or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

#### We depend on our information technology and infrastructure.

We rely on the efficient and uninterrupted operation of information technology systems, including mobile technologies, to manage our operations, to process, transmit and store electronic and financial information, and to comply with regulatory, legal and tax requirements. We also depend on our information technology infrastructure for communications among our personnel, contractors, consultants and vendors. System failures or outages could compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial reporting. Such failures could materially adversely affect our operating results and financial condition.

In addition, we depend on third parties to operate and support our information technology systems. These third parties vary from multi-disciplined to boutique providers, and they may or could have access to our computer networks, mobile networks, and our confidential information. Many of these third parties subcontract or outsource some of their responsibilities to other third parties. As a result, our information technology systems, including those functions that are performed by third parties who are involved with or have access to those systems, are very large and complex. Failure by any of these third-party providers to adequately deliver the contracted services, or maintain confidentiality, could have an adverse effect on our business, which in turn may materially adversely affect our operating results and financial condition. All information technology systems, despite implementation of security measures, may be vulnerable to disability, failures or unauthorized access. If our information technology systems were to fail or be breached, such failure or breach could materially adversely affect our ability to perform critical business functions and sensitive and confidential data could be compromised.

# Our internal information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of what we believe are appropriate security measures on internal information technology systems, our internal information technology systems and those of our CROs and other contractors and consultants may become vulnerable to damage from security breaches and/or unauthorized access. The prevalent use of mobile devices also increases the risk of data security incidents. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual

property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner in order to ensure the confidentiality, integrity and availability of such sensitive information. We have in the past experienced, and may in the future experience, a security breach. Any material system failure or security breach could cause interruptions in our operations and could result in a material disruption of our development programs and our business operations. For example, the loss of data from completed or future preclinical studies or clinical trials could result in significant delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on other third parties for the manufacture of our product candidates and to conduct studies and trials, and similar events relating to their information technology 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 and the further development and commercialization of our product candidates could be significantly delayed.

We may be unable to adequately protect our information technology systems from cyberattacks, which could result in the disclosure of confidential information, damage our reputation, and subject us to significant financial and legal exposure.

Cyberattacks are frequent and may be sophisticated and intense to the point that they are difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, the deployment of harmful malware, denial-of-service, and/or other means to threaten data confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information and trade secrets, and the disclosure of corporate strategic plans. We have in the past experienced, and may in the future experience, a compromise of our data or information technology systems that results in one or more third parties obtaining access to confidential information about our company. Although we devote resources to protect our information technology systems and continue to assess and, as necessitated, enhance our cybersecurity protection, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal or reputational harm to us, or would have a material adverse effect on our operating results and financial condition. Confidential information obtained by third parties in connection with past or future attacks could be used in ways that adversely affect our company or our stockholders.

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

Our operations, and those of our CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we may not have insurance coverage. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters are located in Vancouver, British Columbia, which is near a major earthquake fault. Our operations and financial condition could suffer in the event of a major earthquake or other natural disaster near any of our locations.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by such individuals could include intentional failures

to comply with FDA or international regulations, provide accurate information to the FDA or foreign regulatory authorities, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data timely, completely and accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, 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. Misconduct by third parties could also involve the improper use of information obtained in the course of clinical trials.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. 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, disgorgement, 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. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

# If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in, but are not limited to:

- decreased demand for our product candidates;
- injury to our reputation;
- · withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- · loss of revenue;

- exhaustion of any available insurance and our capital resources;
- · the inability to commercialize any product candidate; and
- a decline in our stock price.

We currently hold liability insurance coverage, but that coverage may not be adequate to cover any and all liabilities that we may incur. We would need to increase our insurance coverage when we begin the commercialization of our product candidates, if ever. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

# Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be significantly limited, or entirely restricted.

As of December 31, 2019, we had gross U.S. federal net tax operating loss carryforwards of \$1.2 million, which are eligible for indefinite carryforwards, and gross state operating loss carryforwards of \$50.7 million expiring in years ranging from 2022 to 2039. We also had U.S. net tax credit carryforwards of \$0.1 million which begin to expire in 2039 and net tax credit carryforwards in a foreign jurisdiction of \$0.4 million which begin to expire in 2038.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income and taxes may be limited. In general, an "ownership change" generally occurs if there is a cumulative change in our ownership by "5% stockholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. An ownership change under Section 382 was deemed to have occurred in 2019 and in 2017. As such, certain tax attributes existing as of the date of the ownership changes are not available for future use. The loss of these attributes did not have any impact on the financial statements since our net U.S. deferred tax assets are offset by a full valuation allowance.

We have experienced ownership changes in the past and may experience ownership changes in the future as a result of future transactions in our stock, some of which may be outside our control. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards, or other pre-change tax attributes, to offset U.S. federal and state taxable income and taxes may be subject to limitations.

We are a U.S.-based multinational company subject to tax in certain U.S. and foreign tax jurisdictions. United States federal, state and local, as well as international tax laws and regulations are extremely complex and subject to varying interpretations. Although we believe that our tax estimates and tax positions are reasonable, there can be no assurance that our tax positions will not be challenged by relevant tax authorities or that we would be successful in any such challenge. If we are unsuccessful in such a challenge, the relevant tax authorities may assess additional taxes, which could result in adjustments to, or impact the timing or amount of, taxable income, deductions or other tax allocations, which may adversely affect our results of operations and financial position.

# Unstable or unfavorable global market and economic conditions may have adverse consequences on our business, financial condition and stock price.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. We cannot assure you that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy and stock price may be adversely affected by

any such economic downturn, volatile business environment or large-scale unpredictable or unstable market conditions, including a prolonged government shutdown. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

# Our quarterly operating results may fluctuate significantly, which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including, but not limited to:

- variations in the level of expense related to our product candidates or future development programs;
- results of preclinical studies and clinical trials, or the addition or termination of preclinical studies, clinical trials or funding support;
- the timing of the release of results from any preclinical studies and clinical trials;
- the timing and amount of milestone and royalty payments to our licensor;
- changes in the competitive landscape or market opportunity for our product candidates;
- our execution of any new collaboration, licensing or similar arrangement, and the timing of payments we may make or receive under such existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- any securities or other litigation in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures,
- strategic investments or changes in business strategy;
- the receipt by any of our product candidates of regulatory approval and market acceptance, and the demand for such product candidates;
- · regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results or expected results from development of our product candidates fall outside the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

#### We face risks related to securities litigation that could result in significant legal expenses and settlement or damage awards.

We may in the future become subject to claims and litigation alleging violations of the securities laws or other related claims, which could harm our business and require us to incur significant costs. For example, on

November 9, 2016, a purported securities class action lawsuit was filed in the United States District Court for the Southern District of New York against us and certain of our executive officers (the New York Lawsuit). The New York Lawsuit was brought by purported stockholders of our company seeking to represent a class consisting of stockholders who purchased stock between July 15, 2015 and June 6, 2016. The New York Lawsuit asserts claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and seeks unspecified damages and other relief. On March 13, 2018, the United States District Court for the Southern District of New York granted the defendants' motion to dismiss and entered a final judgment dismissing the New York Lawsuit with prejudice. The plaintiffs filed an appeal and on December 3, 2018, the United States Court of Appeals for the Second Circuit affirmed the district court's final judgment of dismissal. The plaintiffs did not file a notice or petition for further appellate review in this matter.

Also, on November 18, 2016, a purported securities class action lawsuit was filed in the Superior Court of the State of California for the County of San Mateo against us, certain of our executive officers and directors, and the underwriters for our initial public offering (IPO) of our common stock. On February 9, 2017, a substantially identical putative class action suit was filed in the Superior Court of the State of California for the County of San Mateo asserting the same claims on behalf of the same putative class (the two California lawsuits together, the California Lawsuits). The California Lawsuits were brought by purported stockholders of the company seeking to represent a class consisting of stockholders who purchased stock pursuant to and/or traceable to our Registration Statement on Form S-1. The lawsuits assert claims under Sections 11 and 15 of the Securities Exchange Act of 1934 and seek unspecified damages and other relief. On August 1, 2018, all parties reached a mutually acceptable proposed resolution to the California Lawsuits by way of a mediated settlement, which has been approved by the court. We are generally obliged, to the extent permitted by law, to indemnify our executive officers who are named as defendants in these types of lawsuits. Regardless of the outcome, this or future litigation may require significant attention from management and could result in significant legal expenses, settlement costs or damage awards that could have a material impact on our financial position, results of operations and cash flows.

#### **Risks Related to Government Regulation**

We may be unable to obtain U.S. or foreign regulatory approval of our product candidates, and, as a result, we may be unable to commercialize our product candidates.

Our product candidates are, and any future product candidates that we may develop will be, subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, import, export, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing, distribution, import and export of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be successfully completed before a new drug can be marketed in the United States and in many foreign jurisdictions. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for us or our collaborators to begin selling them.

As a company, we have very limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA or foreign regulatory authorities, and, as a company, we have no experience in obtaining approval of any product candidates. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the initiation of clinical trials, depending upon the type, complexity and novelty of the product candidate. We may encounter delays or rejections during any stage of the regulatory review and approval process based upon the failure of clinical or laboratory data to demonstrate compliance with, or upon the failure of the product candidates to meet, the FDA's or foreign regulatory authorities' requirements for safety, efficacy and quality.

The standards that the FDA and foreign regulatory authorities use when regulating us are not always applied predictably or uniformly and can change. Because the product candidates we are developing may represent a new

class of drug, the FDA and foreign regulatory authorities have not yet established any definitive policies, practices or guidelines in relation to these drugs. The lack of policies, practices or guidelines may hinder or slow review by the FDA or foreign regulatory authorities of any regulatory filings that we may submit. Moreover, the FDA or foreign regulatory authorities may respond to these submissions by defining requirements we may not have anticipated. Such responses could lead to significant delays in the development of our product candidates.

Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA or foreign regulatory authority policy during the period of product development, clinical trials and regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulatory authority, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

In addition, the FDA and/or foreign regulatory authorities may delay, limit, or deny approval of a product candidate for many reasons, including, but not limited to:

- the FDA or foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or foreign regulatory authorities that a product candidate is safe and effective for any indication;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the results of our clinical trials may not demonstrate the safety or efficacy required by the FDA or foreign regulatory authorities for approval;
- · we may be unable to demonstrate the integrity of the clinical trial data to the satisfaction of the FDA or foreign regulatory authorities;
- we may be unable to demonstrate the proper conduct of the clinical trial at all clinical trial sites, by our vendors, and by the Sponsor to the satisfaction of the FDA or foreign regulatory authorities;
- the FDA or foreign regulatory authorities may not approve our companion diagnostic, if a companion diagnostic is required;
- we may encounter difficulties coming to agreement with the FDA or foreign regulatory authorities on a pediatric investigation or study plan or may encounter difficulties meeting the terms of the plan, once agreed;
- the FDA or foreign regulatory authorities may find deficiencies in our manufacturing processes or facilities; and
- the FDA's or foreign regulatory authorities' approval policies or regulations may significantly change in a manner rendering our clinical data insufficient for approval.

Even if we comply with all of the regulatory requirements of the FDA and foreign regulatory authorities, we may not obtain regulatory approval for any of our product candidates in development. If we fail to obtain regulatory approval for any of our product candidates in development, we will have fewer commercialized products than we anticipate and correspondingly lower revenue.

In addition, because there may be approved treatments for some of the diseases for which we may seek approval, in order to receive regulatory approval, we may need to demonstrate through clinical trials that the product

candidates we develop to treat these diseases, if any, are not only safe and effective, but safer or more effective than existing products. Furthermore, in recent years, there has been increased public and political pressure on the FDA with respect to the approval process for new drugs, and the FDA's standards, especially regarding drug safety, appear to have become more stringent.

Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS plan as part of or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

In Europe, the implementation of a new clinical trial regulation that harmonizes the assessment and supervision of clinical trials throughout Europe via a revised European Union clinical trial portal and database has been delayed until late 2020. In December 2019, the EMA management board endorsed the decision to commence the audit of the clinical trial information system (CTIS) in December 2020. The new clinical trial portal and database will be maintained by the EMA in collaboration with the European Commission and the European Union Member States. The objectives of the new regulation include consistent rules for conducting trials throughout the European Union, consistent data standards and adverse events listing, and consistent information on the authorization status. Information on the conduct and results of each clinical trial carried out in the European Union will be made publicly available.

In addition, a new pan-European clinical trial data information database has been created that will be complementary to the database established for pharmacovigilance (Regulation (EC) No 726/2004 with respect to European Union authorized medicinal products). In addition, Commission Implementing Regulation (EU) No 520/2012 outlines the practical implications for marketing authorization holders, national competent authorities, and the EMA. Also, Commission Delegated Regulation (EU) No 357/2014 on post-authorization efficacy studies specifies the situations in which such studies may be required. Post-authorization efficacy studies may be required where concerns relating to some aspects of efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed, or where the understanding of the disease, the clinical methodology or the use of the medicinal product under real-life conditions indicate that previous efficacy evaluations might have to be revised significantly.

Brexit is also expected to disrupt the operation of pre- and post-authorization clinical trial infrastructure, as discussed below.

If we or any collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products by the market. These enforcement actions include, among others:

adverse regulatory inspection findings;

- warning letters;
- · voluntary or mandatory product recalls or public notification or medical product safety alerts to healthcare professionals;
- restrictions on, or prohibitions against, marketing our products;
- restrictions on, or prohibitions against, importation or exportation of our products;
- · suspension of review or refusal to approve pending applications or supplements to approved applications;
- exclusion from participation in government-funded healthcare programs;
- · exclusion from eligibility for the award of government contracts for our products;
- suspension or withdrawal of product approvals;
- · product seizures;
- · injunctions; and
- · civil and criminal penalties and fines.

Furthermore, negotiations around Brexit have caused uncertainty in the current regulatory framework in Europe. Brexit has resulted in the EMA moving from the United Kingdom to the Netherlands. In the United Kingdom, this transition may cause disruption in the administrative and medical scientific links between the EMA and MHRA. Although the government of the United Kingdom has stated its intent to comply with legislation regarding the authorization of medical products as it leaves the European Union, the EMA and the United Kingdom are drawing up contingency plans should a "no deal" exit occur. A "no deal" exit would lead to disruption in the execution of international multi-center clinical trials, the monitoring of adverse events in through pharmacovigilance programs, the evaluation of the benefit-risk profiles of new medicinal products, and determination of marketing authorization. There would also be disruption to the supply and distribution as well as the import/export both of active pharmaceutical ingredients (API) and finished product. Such a disruption would create supply difficulties for ongoing clinical trials and may damage the integrity of the pharmacovigilance database for the safety of new products.

After Brexit, the United Kingdom will no longer automatically comply with the standards of clinical efficacy, safety and chemistry control, and manufacture as applied by the European Medicines Directive. Applications submitted for marketing authorization under the centralized EMA procedure will no longer be automatically validated for authorization in the United Kingdom, and the benefit-risk assessments conducted by the United Kingdom may not be consistent with the EMA conclusions.

The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the European Union and/or the United Kingdom. In view of the current lack of detail and resolution with regard to the Brexit implementation, we are unable to confidently predict the effects of such disruption to the regulatory framework in Europe.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate, and may require us to conduct post-approval clinical studies. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted

distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval.

Moreover, if we obtain regulatory approval for our product candidates, we will only be permitted to market our products for the indication approved by FDA or foreign regulatory authority, and such approval may involve limitations on the indicated uses or promotional claims we may make for our products, or otherwise not permit labeling that sufficiently differentiates our product candidates from competitive products with comparable therapeutic profiles. For example, we will not be able to claim that our products have fewer side effects, or improve compliance or efficacy unless we can demonstrate those attributes to FDA or foreign regulatory authority in comparative clinical trials. Communications that occur prior to obtaining regulatory approval for our product candidates could also be considered promotional and thus may also be subject to certain FDA or foreign regulatory authority requirements.

Later discovery of previously unknown problems with our product candidates, including adverse effects 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 our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or untitled letters;
- holds on clinical trials;
- refusal by the FDA or foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- · product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions, the imposition of civil penalties or criminal prosecution.

The FDA's and foreign regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we 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, and we may not achieve or sustain profitability.

A Fast Track Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

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 FDA Fast Track Designation for a particular indication. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track Designation does not assure any such qualification or ultimate marketing approval by the FDA. We previously announced that the FDA had granted Fast Track designation to momelotinib for the treatment of patients with intermediate/high-risk myelofibrosis who have previously received a JAK inhibitor. Receipt of Fast Track Designation may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw any Fast Track

Designation at any time if it believes that the designation is no longer supported by data from our clinical development program. We may seek Fast Track Designation for any other of our product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates.

If we or any of our independent contractors, consultants, collaborators, manufacturers, vendors or service providers fail to comply with healthcare and data privacy laws and regulations, we or they could be subject to enforcement actions, which could result in penalties and affect our ability to develop, market and sell our product candidates and may harm our reputation.

We are or may in the future be subject to federal, state, and foreign healthcare and data privacy laws and regulations pertaining to, among other things, fraud and abuse and patients' rights. These laws and regulations include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for a healthcare item or service, or the purchasing or ordering of an item or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid;
- the U.S. federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented, claims for payment by government funded programs such as Medicare or Medicaid that are false or fraudulent, and which may apply to us by virtue of statements and representations made to customers or third parties;
- the U.S. federal Health Insurance Portability and Accountability Act (HIPAA), which created additional federal criminal statutes that
  prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud healthcare programs;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), which imposes requirements
  on certain types of people and entities relating to the privacy, security, and transmission of individually identifiable health information, and
  requires notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health
  information;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for
  which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, to report annually to the Centers for
  Medicare & Medicaid Services information related to payments and other transfers of value to physicians, other healthcare providers and
  teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family
  members, which is published in a searchable form on an annual basis; effective January 1, 2022, we will also be required to report on
  transfers of value to physician assistants, nurse practitioners or clinical nurse specialists, certified registered nurse anesthetists, and
  certified nurse-midwives;
- state laws comparable to each of the above federal laws, such as, for example, anti-kickback and false claims laws that may be broader in scope and also apply to commercial insurers and other non-federal payors, requirements for mandatory corporate regulatory compliance programs, and laws relating to patient data privacy and security. Other 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; require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

In the European Union, the GDPR was adopted in May 2016 and took effect on May 25, 2018. The GDPR is intended to harmonize data protection requirements across the European Union Member States by establishing new and expanded operational requirements for entities that process, or control personal data generated in the European Union, including consent requirements for disclosing the way personal information will be used, information retention requirements, notification requirements in the event of a data breach, and other requirements. The United Kingdom enacted the Data Protection Act 2018 to directly enforce the GDPR. The government of the United Kingdom has also stated that the United Kingdom will still abide with the provisions of the GDPR after Brexit. However, in the event of a "no deal" Brexit, it is uncertain whether this commitment will still be met. In the case of a "no deal" Brexit, it is also uncertain whether clinical trial data and pharmacovigilance adverse event data originating from the United Kingdom will be compliant with European Union privacy legislation and whether the data will be incorporated by EMA in the assessment of the ongoing benefit-risk profile and hence continued support of European Union marketing authorizations. The government of the United Kingdom has issued guidance as to how data protection will work in the event of a "no deal" Brexit. The European Union (Withdrawal) Act 2018 will ensure that the fundamental principles, obligations, and rights of GDPR that apply to organizations and data subjects will stay the same after Brexit. New regulations will preserve European Union GDPR standards in domestic law and will:

- Transitionally recognize all EEA countries (including European Union Member States) and Gibraltar as "adequate" to allow data transfers from the United Kingdom to Europe to continue;
- Preserve the effect of existing European Union adequacy decisions on a transitional basis;
- Recognize European Union Standard Contractual Clauses (SCCs) in United Kingdom law and give the ICO the power to issue new clauses:
- Recognize Binding Corporate Rules (BCRs) authorised before Exit day;
- Maintain the extraterritorial scope of the United Kingdom data protection framework; and
- Oblige non-United Kingdom controllers who are subject to the United Kingdom data protection framework to appoint representatives in the United Kingdom if they are processing United Kingdom data on a large scale.

We have certified under the European Union-U.S. Privacy Shield and the Swiss-U.S. Privacy Shield with respect to our transfer of certain personal data from the European Union to the United States. The Privacy Shield program is subject to annual review and may be challenged, suspended or invalidated. At present, the European Union-U.S. Privacy Shield framework and the use of European Union Standard Contractual Clauses, or the Model Clauses, to protect data exports between the European Union and the U.S. are both subject to ongoing legal challenges. Any or all of these court proceedings, or other challenges in the future, may result in a ruling that the industry-standard measures we, and other companies, have taken are no longer sufficient. Additionally, it is possible that the Privacy Shield program may need to be updated by the European Commission and Department of Commerce to take into account the GDPR. As a result, we may be unsuccessful in maintaining legitimate means for our transfer and receipt of personal data from the European Union to the United States and may be at risk of experiencing reluctance or refusal of European or multi-national customers to use our solutions and incurring regulatory penalties, which may have an adverse effect on our business.

If our operations are found to be in violation of any such health care laws and regulations, we may be subject to penalties, including administrative, civil and criminal penalties, monetary damages, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA or foreign regulatory authorities, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and

sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

Any products we develop may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices or healthcare reform initiatives, thereby harming our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Many countries require approval of the sale price of a drug before it can be marketed. The pricing review period begins after marketing or product licensing approval is granted in most cases. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. Although we intend to monitor these regulations, our programs are currently in the early stages of development and we will not be able to assess the impact of price regulations for a number of years. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenues we are able to generate from the sale of the product in that country.

Our ability to commercialize any products successfully also 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 third-party payors. In many jurisdictions, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. If we are not currently capturing the scientific and clinical data that will be required for reimbursement approval, we may be required to conduct additional trials, which may delay or suspend reimbursement approval. Additionally, in the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of reimbursement. Increasingly, the third-party payors, such as government and private insurance plans, who reimburse patients or healthcare providers, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for pharmaceutical products. If the coverage provided for any products we develop is inadequate in light of our development and other costs, our return on investment could be adversely affected.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), established the Medicare Part D program to provide a voluntary prescription drug benefit to patients with disabilities and seniors. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that will provide coverage of outpatient prescription drugs, such as momelotinib, if approved. Medicare Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand

for products for which we receive regulatory approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-government payers.

Historically, Medicare Part D enrollees have had a partial gap in their coverage (known as the "coverage gap" or "donut hole") wherein their coinsurance increases from 25% to a higher percentage (35% for brand drugs in 2018) after they reach an initial coverage limit, and remains at that level until they reach a catastrophic coverage threshold where the coinsurance is considerably reduced. However, beginning in 2019, Medicare Part D enrollees will continue to pay a 25% coinsurance during this interval – the same percentage that they were responsible for before they reached the initial coverage limit – thereby closing the coverage gap. The cost of closing the coverage gap is being borne by innovator companies and the government through subsidies. Beginning in 2011, each manufacturer of a drug approved under an NDA was required to enter into a Medicare Part D coverage gap discount agreement and provide a 50% discount on those drugs dispensed to Medicare Part D enrollees in the coverage gap, in order for its drugs to be reimbursed by Medicare Part D. The Bipartisan Budget Act of 2018 increased the manufacturer's subsidy under this program from 50% to 70% of the negotiated price, beginning in 2019.

Certain products we develop, such as our lead product candidate, momelotinib, if approved, may need to be administered under the supervision of a physician on an outpatient basis. Under applicable U.S. law, certain drugs that are not usually self-administered (including certain injectable drugs) may be eligible for coverage under the Medicare Part B program if:

- they are incident to a physician's services;
- they are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice; and
- they have been approved by the FDA and meet other requirements of the statute.

There may be significant delays in obtaining coverage for newly-approved products, and coverage may be more limited than the purposes for which the drug is approved by the FDA or foreign regulatory authorities. Moreover, eligibility for coverage does not imply that any drug will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent.

Reimbursement may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for products 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 products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare Part D coverage policy and payment limitations in setting their own reimbursement rates. However, no uniform policy requirement for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for new drugs that we develop and for which we obtain regulatory approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our financial condition.

We believe that the efforts of governments and third-party payors to contain or reduce the cost of healthcare and legislative and regulatory proposals to broaden the availability of healthcare will continue to affect the business

and financial condition of oncology companies. A number of legislative and regulatory changes in the healthcare system in the United States and other major healthcare markets have been proposed in recent years, and such efforts have expanded substantially in recent years. These developments have included prescription drug benefit legislation that was enacted and took effect in January 2006, healthcare reform legislation enacted by certain states, and major healthcare reform legislation that was passed by Congress and enacted into law in the United States in 2010. The U.S. Congress and the Trump administration have similarly expressed concerns over the pricing of pharmaceutical products and there can be no assurance as to how this scrutiny will impact future pricing of pharmaceutical products generally. To date, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. While these and any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, in May 2018 the Trump administration published the American Patients First Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs intended to lower prescription drug prices, which the Department of Health and Human Services is beginning to roll out. Future developments could, directly or indirectly, affect our ability to sell our products, if approved, at a favorable price.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act (PPACA), contains provisions that affect companies in the pharmaceutical industry and other healthcare related industries by imposing additional costs and changes to business practices. Provisions affecting pharmaceutical companies include the following.

- mandatory rebates for drugs sold into the Medicaid program were increased, and the rebate requirement was extended to drugs used in risk-based Medicaid managed care plans;
- the 340B Drug Pricing Program under the Public Health Services Act was extended to require mandatory discounts for drug products sold to certain critical access hospitals, cancer hospitals and other covered entities;
- · expansion of eligibility criteria for Medicaid programs;
- expansion of entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- pharmaceutical companies are required to offer discounts on brand-name drugs to patients who fall within the Medicare Part D coverage gap, commonly referred to as the "donut hole"; the Bipartisan Budget Act of 2018 increased the manufacturer's subsidy under this program from 50% to 70% of the negotiated price, beginning in 2019; and

 pharmaceutical companies are required to pay an annual non-tax-deductible fee to the federal government based on each company's market share of prior year total sales of branded products to certain federal healthcare programs, such as Medicare, Medicaid, Department of Veterans Affairs and Department of Defense. Since we expect our branded pharmaceutical sales, if any of our products are approved, to constitute a small portion of the total federal health program pharmaceutical market, we do not expect this annual assessment to have a material impact on our financial condition.

There have been judicial and Congressional challenges and amendments to certain aspects of the PPACA. President Trump has suggested that he plans to seek repeal of all or portions of the PPACA and indicated that Congress should replace the PPACA with new legislation, and in 2017, President Trump issued the Executive Order Promoting Healthcare Choice and Competition, directing certain federal agencies to modify their implementation of the PPACA. We expect there will be additional challenges, amendments and modifications to the PPACA in the future, including potential repeal of PPACA in full or in part. The full effect of the U.S. healthcare reform legislation on our business activities is unknown. The financial impact of the U.S. healthcare reform legislation will depend on a number of factors, including but not limited to, the policies reflected in implementing regulations and guidance and changes in sales volumes for products affected by the new system of rebates, discounts and fees. The legislation may also have a positive impact on our future net sales, if any, by increasing the aggregate number of persons with healthcare coverage in the United States. Further, new litigation is currently pending before the U.S. Supreme Court to invalidate certain provisions of the PPACA.

Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future. Further federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

# Our ability to obtain services, reimbursement or funding may be impacted by possible reductions in federal spending in the United States as well as globally.

U.S. federal government agencies currently face potentially significant spending reductions. Under the Budget Control Act of 2011, the failure of Congress to enact deficit reduction measures of at least \$1.2 trillion for the years 2013 through 2021 triggered automatic cuts to most federal programs. These cuts would include aggregate reductions to Medicare payments to providers of up to two percent per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2025 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, which was enacted on January 1, 2013, among other things, reduced Medicare payments to several providers, including hospitals and imaging centers. The full impact on our business of these automatic cuts is uncertain.

If government spending is reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve drug research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop. Any reductions in government spending in countries outside the United States may also impact us negatively, such as by limiting the functioning of international regulatory agencies in countries outside the United States or by eliminating programs on which we may rely.

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

Obtaining and maintaining regulatory approval for 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 for a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

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 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.

If we or our third-party manufacturers 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.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by ourselves and our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States and abroad governing laboratory procedures and the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental, health and safety laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

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.

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

# The Tax Cuts and Jobs Act could increase our tax burden and adversely affect our business and financial condition.

In December 2017, the U.S. government enacted comprehensive tax legislation referred to as the Tax Cuts and Jobs Act (Tax Act) that includes significant changes to the taxation of business entities. These changes include,

among others, (i) a permanent reduction to the corporate income tax rate, (ii) revisions to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017 (iii) a partial limitation on the deductibility of business interest expense, (iv) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a participation exemption system (along with certain rules designed to prevent erosion of the U.S. income tax base) and (v) a one-time tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate.

In addition, beginning in 2022, the tax legislation will require U.S. research and experimental expenditures to be capitalized and amortized ratably over a five-year period. Any such expenditures attributable to research conducted outside the U.S. must be capitalized and amortized over a 15-year period. Further, the Tax Act, among other things, reduces the orphan drug credit from 50% to 25% of qualifying expenditures. When and if we become profitable, this amortization of research and experimental expenditures and reduction in orphan drug tax credits may result in an increased federal income tax burden, as it may cause us to pay federal income taxes earlier under the revised tax law than under the prior law and, despite being partially off-set by a reduction in the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, may increase our total federal tax liability.

#### **Risks Related to Our Intellectual Property**

We depend on intellectual property licensed from CPF and Carna, and the termination of these licenses could result in the loss of significant rights, which would harm our business.

Pursuant to a license agreement with CPF, we hold an exclusive license from CPF to use certain patented technology, including certain patent rights, know-how and materials related to SRA737. Either party may terminate the agreement if the other party materially breaches the agreement, subject to certain cure provisions, and CPF may terminate the agreement in certain limited circumstances. We may also terminate the agreement at any time upon 90 days' prior written notice to CPF. Additionally, pursuant to a license agreement with Carna, we hold an exclusive license from Carna to use certain patented technology, including certain patent rights and know-how related to SRA141. Carna may terminate the agreement in the event of our material breach, subject to certain cure provisions, and we may terminate the agreement at any time upon 30 days' prior written notice to Carna.

Disputes may arise between us and our licensors regarding intellectual property subject to these license agreements, including with respect to:

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

Any disputes with our licensors over intellectual property that we have licensed from them may prevent or impair our ability to maintain our current licensing arrangements. We depend on these licensed technologies and

products to develop our product candidates. Termination of our license agreements could result in the loss of significant rights and could materially harm our ability to further develop and commercialize our product candidates.

If we are not able to obtain and enforce patent protection for our technologies or product candidates, development and commercialization of our product candidates may be adversely affected.

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, methods used to manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. Our licensors have filed, and we will continue to file, patent applications directed to the compositions of matter and methods of use related to various aspects of our product candidates.

We and our current or future licensors and licensees may not be able to apply for or prosecute patents on certain aspects of our product candidates or technologies at a reasonable cost in a timely fashion or at all. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensors, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using, and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our issued or granted patents will not later be found to be invalid or unenforceable or that any issued or granted patents will include claims that are sufficiently broad to cover our product candidates or technologies or to provide meaningful protection from our competitors. Moreover, the patent position of oncology companies can be highly uncertain because it involves complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely impact our position in the market.

The U.S. Patent and Trademark Office (USPTO) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in oncology patents. Moreover, changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. While we will endeavor to try to protect our product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and sometimes unpredictable.

Further, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed (or 20 years after the filing date of the first non-provisional US patent application to which it claims priority). Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product candidate limits the time during which we can market a product candidate under patent protection, which may particularly affect the profitability of our early-stage product candidates.

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

In addition to seeking patent protection for certain aspects of our product candidates and technologies, we also consider trade secrets, including confidential and unpatented know-how important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us.

Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

Numerous recent changes to the patent laws and proposed changes to the rules of the USPTO may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the Leahy-Smith America Invents Act (AIA) enacted in 2011 involves significant changes in patent legislation. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

Further, the Supreme Court has ruled on several patent cases in recent years, some of which cases either narrow the scope of patent protection available in certain circumstances or weaken the rights of patent owners in certain situations. These changes have led to increasing uncertainty with regard to the scope and value of our issued patents and to our ability to obtain patents in the future.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to

invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification derivation and opposition proceedings in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether.

We, our licensors or any future strategic partners may become subject to third-party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights.

We, our licensors or any future strategic partners may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights that prevent us from developing and commercializing our products. If we, our licensors or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay substantial damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. In addition, we, our licensors or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to conti

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products or our technology, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during

patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Such a loss of patent protection could have a material adverse impact on our business. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights.

In addition, in an infringement proceeding, a court may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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. 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.

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

#### We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor

the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to oncology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates and technologies or we could lose certain rights to grant sublicenses.

In connection with our acquisition of momelotinib from Gilead, we are required to make aggregate milestone payments of up to \$190.0 million to Gilead upon the achievement of certain regulatory and commercial milestones, as well as low double-digit to high-teens percent tiered combined royalties based upon net sales and additional tiered milestone payments upon reaching certain sales milestones. If we breach any of these obligations, we may be required to indemnify the Seller, subject to certain limitations set forth in the momelotinib purchase.

Additionally, our current license agreements impose, and any future licenses we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement, and other obligations on us. For example, we are required to use commercially reasonable efforts to develop and commercialize licensed products, and are required to pay CPF and Carna milestone payments in an aggregate amount of up to \$319.5 and \$270.0 million, respectively, based upon the achievement of certain developmental, regulatory and commercial milestones of SRA737 and SRA141, including milestone payments of \$7.5 and \$12.0 million that would be due to CPF upon the dosing of the first patient in the first Phase 1 trial of SRA737 in the United States and upon the dosing of the first patient of a randomized Phase 2 trial of SRA737, respectively (in the event that the milestone payment for Phase 2 becomes due, but no milestone payment for Phase 1 has been paid, then the milestone payment for Phase 1 will become due and payable contemporaneously with the payment for the Phase 2 milestone for an aggregate payment of \$19.5 million), and a milestone payment of \$4.0 million to Carna upon dosing of the first patient in the first Phase 1 clinical trial for SRA141. We are also required to pay CPF tiered high single-digit to low double-digit royalties on the net sales of SRA737 and to pay Carna tiered single-digit royalties on the net sales of SRA141. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. We may also be required to negotiate to return our licensed intellectual property related to SRA737 to CPF if we cease or scale back development and commercialization of SRA737 for oncology-related indications, and we may be unsuccessful in any such renegotiation efforts for SRA737 or any other of our product candidates Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, we may be required to pay significant milestone and royalty payments, depending on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other oncology companies. We may be subject to claims that we or our

employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

# Risks Related to Ownership of Our Common Stock

The market price of our common stock has been and may continue to be volatile, and you may be unable to sell your shares at or above the price at which you purchased them.

The market price of our common stock has been and may continue to be subject to wide fluctuations. For example, we experienced a significant decrease in our stock price after we announced the suspension of the development of our former lead product candidate PNT2258 and the DNAi platform in June 2016 and after we announced the preliminary clinical data from our two Phase 1/2 studies of SRA737 in June 2019. Factors affecting the market price of our common stock include, but are not limited to:

- the timing and results of development activities related to our product candidates;
- our capital requirements, anticipated financings and the related dilution;
- the commencement, enrollment or results of future clinical trials we may conduct, or changes in the development status of our product candidates:
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect
  to the applicable regulatory authority's review of such filings;
- disputes with CPF or Carna regarding our licensed technology and products, or with Gilead regarding our acquisition of momelotinib and assumption of the related clinical trials;
- our ability to acquire or in-license new product candidates to grow our pipeline;
- adverse results or delays in preclinical studies or clinical trials;
- · changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed, or to out-license our product candidates or technologies on favorable terms or at all;
- our failure to commercialize our product candidates;
- · additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- the size and growth of our initial target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- · our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;

- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and oncology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Securities class action litigation is often instituted against companies following periods of volatility in the market price of a company's securities. For example, we have previously vigorously defended purported securities class action lawsuits against us and certain of our executive officers. This type of litigation could result in substantial costs and a diversion of management's attention and resources, which could harm our business, operating results or financial condition.

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

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (JOBS Act) enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 (Section 404) of the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. 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.

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 our 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 requires the market value of our common stock that is held by non-affiliates to exceed \$700 million as of the prior June 30th, whichever is earliest; and (ii) the date on which we have issued more than \$1 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, 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.

# We incur significantly increased costs and devote substantial management time as a result of operating as a public company.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the stock exchange upon which our common stock is listed and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. 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 are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404.

Additionally, we have in the past and may in the future identify material weaknesses or significant deficiencies in internal control over financial reporting. Under standards established by the Public Company Accounting Oversight Board, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. We cannot assure you that there will not be additional material weaknesses or significant deficiencies that our independent registered public accounting firm or we will identify. If we identify such issues or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected and we may be unable to maintain compliance with the Nasdaq Stock Market listing requirements.

Provisions in our restated certificate of incorporation and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our restated certificate of incorporation and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan (also known as a "poison pill");
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- · prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the securities or industry analysts who publish research about us downgrade our stock or publish inaccurate or unfavorable evaluations of our company or our stock, the price of our stock could decline. If one or more of these analysts cease coverage of our company, our stock may lose visibility in the market, which in turn could cause our stock price to decline.

Certain of our 5% stockholders hold a majority of the voting power and may be able to exert significant control over matters subject to stockholder approval.

As of January 31, 2020, our executive officers, directors and 5% stockholders beneficially owned a majority of our outstanding voting shares. Further, four of our current directors are affiliates of certain 5% stockholders. Therefore, these holders may have the ability to influence us through their ownership position and through representation on our board of directors as they hold half of the board seats. These holders may be able to determine all matters requiring stockholder approval. For example, these holders may be able to control the vote with respect to elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock.

# The issuance or sale of shares of our common stock, or rights to acquire shares of our common stock could depress the trading price of our common stock.

We may conduct future offerings of our common stock, preferred stock or other securities that are convertible into or exercisable for our common stock to finance our operations or fund acquisitions, or for other purposes. If we issue additional shares of our common stock or rights to acquire shares of our common stock, if any of our existing stockholders sells a substantial amount of our common stock, or if the market perceives that such issuances or sales may occur, then the trading price of our common stock, and, accordingly, the trading price of our common stock may significantly decrease. In addition, our issuance of additional shares of common stock, including upon exercise of our outstanding warrants, will dilute the ownership interests of our existing common stockholders.

## Item 1B. Unresolved Staff Comments.

None.

## Item 2. Properties.

Our corporate headquarters are located in Vancouver, British Columbia, Canada, where we occupy approximately 8,300 square feet of office space under lease that expires in February 2023, with the option to extend for an additional 5 years. We believe that this facility is sufficient to meet our current needs.

## Item 3. Legal Proceedings.

From time to time, we may become subject to other legal proceedings, claims and litigation arising in the ordinary course of business. In addition, we may receive letters alleging infringement of patents or other intellectual property rights. We are not currently a party to any other material legal proceedings, nor are we aware of any pending or threatened litigation that, in the opinion of our management, would have a material adverse effect on our business, operating results, cash flows or financial conditions should such litigation be resolved unfavorably. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

## Item 4. Mine Safety Disclosures.

Not applicable.

## PART II

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

Our common stock is listed on the Nasdaq Global Market. Our stock trades under the symbol "SRRA". As of February 26, 2020, there were 60 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

# **Dividend Policy**

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 to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future.

## **Recent Sales of Unregistered Securities**

None.

## Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

# **Securities Authorized for Issuance under Equity Compensation Plans**

The information called for by this item is incorporated by reference to our Proxy Statement for the 2020 Annual Meeting of Stockholders. See Part III, Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

## Item 6. Selected Consolidated Financial Data.

The following tables set forth certain selected consolidated financial data. You should read the selected consolidated financial data below in conjunction with Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Year Ended December 31,						
	2019	2018	2017	2016	2015		
		(in thousands e	xcept share and p	er share data)			
Consolidated Statements of Operations Data:							
Operating expenses(1):							
Research and development	\$ 53,249	\$ 41,078	\$ 30,157	\$ 33,895	\$ 26,356		
General and administrative	13,743	14,339	12,462	14,180	9,472		
Total operating expenses	66,992	55,417	42,619	48,075	35,828		
Loss from operations	(66,992)	(55,417)	(42,619)	(48,075)	(35,828)		
Other income (expense), net:							
Changes in fair value of warrant liabilities	(20,926)	_		_	(17,443)		
Other income (expense), net	(517)	1,780	760	351	66		
Total other income (expense), net	(21,443)	1,780	760	351	(17,377)		
Loss before provision for (benefit from) income taxes, net	(88,435)	(53,637)	(41,859)	(47,724)	(53,205)		
Provision for (benefit from) income taxes, net	(160)	(302)	156	143	55		

	Year Ended December 31,						
	2019	2018	2017	2016	2015		
		(in thousands ex	xcept share and per	r share data)			
Net loss	(88,275)	(53,335)	(42,015)	(47,867)	(53,260)		
Adjustment to redemption value on redeemable convertible preferred stock	_		_	_	(374,015)		
Series B and B-1 redeemable convertible preferred stock dividend	_	_	_	_	(5,543)		
Series C and D redeemable convertible preferred stock dividend					(20,366)		
Net loss attributable to common stockholders	\$ (88,275)	\$ (53,335)	\$ (42,015)	\$ (47,867)	\$ (453,184)		
Net loss per share, basic and diluted(2)	\$ (30.30)	\$ (30.16)	\$ (33.68)	\$ (63.32)	\$(1,258.89)		
Weighted-average shares used in computing net loss per share, basic and							
diluted(2)	2,913,487	1,768,480	1,247,482	756,006	359,988		

(1) Includes the following stock-based compensation:

		Year Ended December 31,				
	2019	2018	2017	2016	2015	
		(in thousands)				
Stock-based compensation:						
Research and development	\$3,873	\$4,499	\$3,966	\$3,635	\$1,846	
General and administrative	1,822	2,297	1,939	1,875	1,340	
Total stock-based compensation	\$5,695	\$6,796	\$5,905	\$5,510	\$3,186	

(2) Basic and diluted net loss per share is computed based on the weighted-average number of shares of common stock outstanding during each period. In 2019, basic and diluted net loss per share is computed based on the weighted-average number of common stock and preferred stock with characteristics of common stock outstanding during the period. All share and per share data in this table has been adjusted to reflect the 1-for-40 reverse stock split effected on January 22, 2020. For additional information, see Notes 1 and 3 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

			December 31,		
	2019	2018	2017	2016	2015
			(in thousands)		
Consolidated Balance Sheets Data:					
Cash and cash equivalents	\$ 147,528	\$ 106,046	\$ 100,348	\$ 109,007	\$ 150,180
Working capital <sup>(1)</sup>	85,288	98,653	94,253	102,625	144,456
Total assets	151,328	109,469	102,198	110,973	152,768
Operating lease liability	374	_	_	_	_
Term loan	_	4,891	_	_	_
Total liabilities(1)	64,983	14,990	7,472	7,725	7,397
Accumulated deficit	(765,687)	(677,412)	(624,077)	(582,054)	(534,187)
Total stockholders' equity	86,345	94,479	94,726	103,248	145,371

<sup>(1)</sup> At December 31, 2019, warrant liabilities of \$45,935 and a securities issuance obligation of \$10,485 were included in current liabilities. See Note 8 and Note 11 to the financial statements under Item 8 of this Form 10-K.

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

The following discussion contains management's discussion and analysis of our financial condition and results of operations and should be read together with the historical consolidated financial statements and the notes thereto included in Part II, Item 8 "Consolidated Financial Statements and Supplementary Data." This discussion and other parts of this Annual Report contain forward-looking statements that reflect our plans, objectives, expectations, intentions and beliefs and involve numerous risks and uncertainties, including but not limited to those described in the "Risk Factors" section of this Annual Report. Actual results may differ materially from those contained in any forward-looking statements. You should carefully read "Special Note Regarding Forward-Looking Statements" and Part I, Item 1A, "Risk Factors."

## Overview

We are a late stage drug development company focused on advancing our lead product candidate, momelotinib, a potent, selective and orally-bioavailable JAK1 (Janus kinase 1), JAK2 (Janus kinase 2) and ACVR1 (Activin A receptor type 1) inhibitor with a potentially differentiated therapeutic profile for the treatment of myelofibrosis. We have a highly experienced management team with a proven track record of success in hematology and oncology drug development. We are oriented towards achieving the successful registration and commercialization of momelotinib.

During the third quarter of 2018, we acquired momelotinib from Gilead Sciences, Inc. (Gilead). Momelotinib has been investigated in two completed Phase 3 trials for the treatment of myelofibrosis. Data from these trials indicate a potentially differentiated therapeutic profile encompassing anemia-related clinical benefits, as well as achieving constitutional symptom control benefits and substantive splenic volume reductions.

In December 2018, we reported new data for momelotinib collated from the two completed SIMPLIFY Phase 3 clinical trials and a translational biology study in transfusion dependent patients with myelofibrosis. Data from the latter study were also concurrently presented in a poster at the 60<sup>th</sup> American Society of Hematology Annual Meeting & Exposition in San Diego, California. We reported aggregated transfusion independence responses from more than 150 intermediate and high-risk transfusion dependent myelofibrosis patients demonstrating robust and consistent response rates within and across the clinical studies. More than 44% of these patients became transfusion free for at least 12 weeks and nearly 50% were transfusion independent for at least 8 weeks.

In the second quarter of 2019, we announced that we had obtained regulatory clarity with the FDA concerning the design of a Phase 3 clinical trial intended to support potential registration of momelotinib. We also announced that the FDA had granted Fast Track designation to momelotinib for the treatment of patients with intermediate/high-risk myelofibrosis who have previously received a JAK inhibitor.

Following receipt of this clarity, we announced the design of the MOMENTUM Phase 3 clinical trial in myelofibrosis, which we subsequently launched in the fourth quarter of 2019. MOMENTUM is a randomized double-blind trial designed to enroll 180 myelofibrosis patients who are symptomatic and anemic and have been treated previously with a JAK inhibitor. The Primary Endpoint of the trial is the Total Symptom Score (TSS) response rate of momelotinib compared to danazol at Week 24 (99% power; p-value < 0.05). Danazol has been selected as an appropriate treatment comparator given its use to ameliorate anemia in myelofibrosis patients, as recommended by NCCN (National Comprehensive Cancer Network) and ESMO (European Society for Medical Oncology) guidelines. Patients will be randomized 2:1 to receive either momelotinib or danazol. After 24 weeks of treatment, patients on danazol will be allowed to crossover to receive momelotinib.

During the fourth quarter of 2019, we reported new analyses of red blood cell (RBC) transfusion data from SIMPLIFY-1, a double-blind Phase 3 trial of momelotinib head-to-head versus ruxolitinib in JAK inhibitor naïve patients, which were presented in a poster by Dr. Ruben Mesa, Director of the Mays Cancer Center, home to UT Health San Antonio MD Anderson Cancer Center, at the 61st American Society of Hematology (ASH)

Annual Meeting in Orlando, Florida. These analyses demonstrated that patients who received momelotinib had significantly decreased transfusion requirements compared to those treated with ruxolitinib, including an odds ratio of nearly 10 for receiving no transfusions during the 24-week study period. Transfusion dependency and moderate to severe anemia are critical negative prognostic factors for overall survival in myelofibrosis.

Our portfolio also includes two DNA Damage Response (DDR) assets, consisting of SRA737 and SRA141.

- SRA737 is our potent, highly selective, orally bioavailable small molecule inhibitor of Checkpoint kinase 1 (Chk1). Chk1 is a key regulator of cell cycle progression and the DDR network. SRA737 is being evaluated across multiple indications in two Phase 1/2 trials, as monotherapy and when potentiated by non-cytotoxic low-dose gemcitabine (LDG), a potent extrinsic inducer of replication stress. At the 2019 American Society of Clinical Oncology (ASCO) annual meeting, we reported preliminary data from these trials, which included anticancer activity across multiple indications.
- SRA141 is our potent, selective, orally bioavailable small molecule inhibitor of Cell division cycle 7 kinase (Cdc7). We successfully
  completed the IND filing process with the FDA for SRA141 in 2018.

We wholly own momelotinib, subject to future milestone payments and royalties (see Item 1. Business—"Asset Purchase Agreement") and retain the global commercialization rights to SRA737 and SRA141.

Since inception, we have devoted substantially all of our resources to research and development activities, including the clinical development of our current product candidates, momelotinib, SRA737 and SRA141, and our former lead product candidate PNT2258, and to provide general and administrative support for these operations. We have never generated revenue and have incurred significant net losses since inception. Our net losses were \$88.3 million, \$53.3 million and \$42.0 million for the year ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of \$765.7 million, of which approximately \$428 million pertained to the revaluation and conversion of redeemable convertible preferred stock upon our initial public offering in July 2015.

During the second quarter of 2019, we announced plans to prioritize our existing resources on the development of momelotinib, our lead product candidate. We also announced we have launched a campaign exploring non-dilutive strategic options to support any future continued development of our portfolio of DDR assets, consisting of SRA737 and SRA141.

We expect to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- invest to further develop our lead product candidate, momelotinib;
- hire additional clinical, scientific, drug development and management personnel, as well as personnel to support any future commercialization efforts;
- invest in scaling our manufacturing capacity to support development and our global commercialization strategy;
- seek regulatory and marketing approvals for any product candidates that we may develop;
- achieve regulatory milestones that trigger payments due under our Asset Purchase Agreement with Gilead;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any drugs for which we may obtain marketing approval;
- acquire or in-license additional product candidates and technologies;
- · develop additional product candidates;
- defend against potential lawsuits or other legal issues;

- maintain, expand and protect our intellectual property portfolio; and
- add operational, financial and management information systems and personnel to continue to operate as a public company.

In November 2019, we completed an underwritten public offering of an aggregate of (i)103,000 shares of Series A convertible voting preferred stock (Series A preferred Stock) that all converted into 7,803,273 shares of common stock in January 2020, (ii) Series A warrants to purchase up to an aggregate of 7,802,241 shares of our common stock at an exercise price equal to \$13.20, and (iii) Series B warrants to purchase up to an aggregate of 2,574,727 shares of common stock. Each share of Series A Preferred Stock and the accompanying Series A and Series B warrants were issued at a combined price to the public of \$1,000. The aggregate net proceeds received by us from the offering were \$97.7 million, net of underwriting discounts and commissions and offering expenses. The Series B warrants may only be exercised by paying the exercise price in cash, and if fully exercised would amount to approximately \$34.0 million in proceeds to us.

We have funded our operations to date primarily from the issuance and sale of our common stock and convertible voting preferred stock through public offerings, and our convertible and redeemable convertible preferred stock in private financings and, to a lesser extent, through debt financings and exercises of our preferred stock warrants issued in private financings. As of December 31, 2019, we had cash and cash equivalents of \$147.5 million.

On January 21, 2020, our shareholders approved an amendment to our certificate of incorporation to effect a reverse split of our common stock (Reverse Stock Split). Following the approval of our shareholders, on January 21, 2020, our board of directors approved the specific ratio for the Reverse Stock Split, which became effective on January 22, 2020, at 1-for-40. The authorized shares and par value of the common and preferred stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock, warrants for common stock, options for common stock and per share amounts contained in this annual report and the consolidated financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented.

# **Components of Statements of Operations**

## **Operating Expenses**

Research and Development

Research and development expenses consist primarily of the following:

- fees, milestone payments or other expenses incurred in connection with license and asset purchase agreements and their related amendments:
- personnel-related costs, which include salaries, benefits, stock-based compensation, recruitment fees and travel costs;
- costs associated with research and preclinical studies, clinical trials, regulatory activities and manufacturing activities to support clinical activities;
- fees paid to external service providers that conduct certain research and development, clinical and manufacturing activities on our behalf;
   and
- facility-related costs, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization expenses and other supplies.

The largest recurring component of our total operating expenses has historically been our investment in research and development activities, including the development of our lead product candidate momelotinib and SRA737 and SRA141. We expect our research and development expenses will increase over the next few years as we advance momelotinib, achieve regulatory milestones that trigger payments due under our Asset Purchase

Agreement with Gilead, pursue regulatory approval of momelotinib in the United States and other jurisdictions, expand our portfolio of product candidates and prepare for potential commercialization, which will require a significant investment in areas related to contract manufacturing and inventory buildup.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for our lead product candidate, momelotinib. The probability of success of our product candidates may be affected by numerous factors, including clinical data, regulatory developments, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization of momelotinib.

## General and Administrative

General and administrative expenses consist of personnel-related costs, facility-related costs, business insurance allocated expenses and professional fees for services, including legal, patent prosecution and maintenance, human resources, audit and accounting services. Personnel-related costs consist of salaries, benefits, stock-based compensation, recruitment fees, severance costs and travel costs.

We expect to incur additional expenses associated with supporting our growing research and development activities, preparing for potential commercialization, continuing to operate as a public company and other administration and professional services.

## Other Income (Expense), net

## Changes in Fair Value of Warrant Liabilities

Our common stock warrants issued in connection with our November 2019 financing are classified as liabilities on our consolidated balance sheets and, as such, are re-measured to fair value at each balance sheet date, with the corresponding gain or loss from the adjustment recorded in the consolidated statement of operations. The changes in the fair value is directly attributable to the change in the fair value of the underlying stock.

# Other Income (Expense), net

Other income (expense), net primarily consists of (i) interest earned on our cash and cash equivalents, (ii) interest expense, including final payment and prepayment fees and the full non-cash amortization of debt issuance costs, associated with our term loan, (iii) offering expenses incurred pertaining to the issuance of warrants, and (iv) foreign currency exchange gains and losses related to transactions and monetary asset and liability balances denominated in currencies other than the U.S. dollar. Foreign currency exchange gains and losses may fluctuate in the future due to changes in foreign currency exchange rates.

# Provision for (Benefit from) Income Taxes, net

Provision for (benefit from) income taxes, net consists of federal and state income taxes in the United States, income tax benefit resulting from research and development tax credits in Canada, income taxes in Canada and Australia, as well as deferred income taxes reflecting the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and changes in related valuation allowance.

We did not record a provision for U.S. federal income taxes for the year ended December 31, 2019. Our tax benefit relates to research and development tax credits in Canada and our income tax provision relates to income taxes in Canada and Australia. Our net U.S. deferred tax assets continue to be offset by a full valuation allowance.

## **Results of Operations**

A discussion regarding our financial condition and results of operations for the year ended December 31, 2018 compared to the year ended December 31, 2017 is included in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on February 28, 2019.

## Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

	Year I Decem		Chan	ge	
	2019	2018	\$	%	
	(in thous	(in thousands, except percentages)			
Operating expenses:					
Research and development	\$ 53,249	\$ 41,078	\$ 12,171	30%	
General and administrative	13,743	14,339	(596)	(4%)	
Total operating expenses	66,992	55,417	11,575	21%	
Loss from operations	(66,992)	(55,417)	(11,575)	21%	
Other income (expense), net:					
Changes in fair value of warrant liabilities	(20,926)	_	(20,926)	(100%)	
Other income (expense), net	(517)	1,780	(2,297)	(129%)	
Total other income (expense), net	(21,443)	1,780	(23,223)	(1,305%)	
Loss before benefit from income taxes, net	(88,435)	(53,637)	(34,798)	65%	
Benefit from income taxes, net	(160)	(302)	142	(47%)	
Net loss	\$(88,275)	\$(53,335)	\$(34,940)	66%	

## Research and Development

Research and development expenses increased \$12.2 million, from \$41.1 million in 2018 to \$53.2 million in 2019. In addition to a non-cash charge of \$10.5 million pertaining to the obligation to issue common stock and a warrant in consideration for meaningfully reduced royalty rates and elimination of a near term milestone payment in an amendment to the Asset Purchase Agreement with Gilead, the increase was primarily due to costs related to momelotinib, including a \$12.2 million increase in clinical trial and development costs, a \$2.5 million increase in third party manufacturing costs and a \$1.4 million increase in personnel-related and allocated overhead costs for the year ended December 31, 2019. These increased costs were partially offset by a \$3.0 million upfront fee paid to Gilead to acquire momelotinib during the year end December 31, 2018 and decreases in SRA737 and SRA141 costs, including a \$5.0 million decrease in clinical trial costs primarily related to SRA737, a \$4.3 million decrease in third party manufacturing costs and a \$2.1 million decrease in research and preclinical costs for the year ended December 31, 2019.

## General and Administrative

General and administrative expenses decreased \$0.6 million, from \$14.3 million in 2018 to \$13.7 million in 2019. The decrease was attributable to a \$0.5 million decrease in personnel-related and allocated overhead costs and a \$0.2 million decrease in business development costs, partially offset by a \$0.1 million increase in professional fees for the year ended December 31, 2019.

# Changes in Fair Value of Warrant Liabilities

The changes in the fair value of our warrant liabilities were directly attributable to the change in the fair value of the underlying stock.

# Other Income (Expense), net

Other income (expense), net increased \$2.3 million, from \$1.8 million of other income, net in 2018 to \$0.5 million of other expense, net in 2019. The increase was primarily attributable to offering expenses of \$1.3 million pertaining to warrants issued in the 2019 public offering, \$0.7 million increase in interest expense incurred on the term loan, a \$0.2 million decrease in interest income due to a lower average cash and cash equivalents balance during the year ended December 31, 2019, and a \$0.1 million increase in foreign exchange loss for the year ended December 31, 2019.

## Benefit from Income Taxes, net

Net benefit from income taxes was \$0.2 million in 2019, compared to \$0.3 million in 2018. The net benefit from income taxes during the year ended December 31, 2019 primarily represented benefit from foreign research and development tax credits.

#### **Liquidity and Capital Resources**

## **Capital Resources**

Since our inception, we have never generated revenue and have incurred significant net losses. We have funded our operations to date primarily from the issuance and sale of our common stock and convertible voting preferred stock through public offerings, our convertible and redeemable convertible preferred stock in private financings and, to a lesser extent, through debt financings and exercises of our preferred stock warrants issued in private financings. Our net losses were \$88.3 million and \$53.3 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of \$765.7 million, of which approximately \$428 million pertained to the revaluation and conversion of redeemable convertible preferred stock upon our initial public offering in July 2015. Our principal sources of liquidity as of December 31, 2019 were cash and cash equivalents of \$147.5 million.

In March 2018, we completed an underwritten public offering of an aggregate of 546,250 shares of common stock, at a price to the public of \$90.00 per share. The aggregate net proceeds received by us from the offering were \$46.0 million, net of underwriting discounts and commissions and offering expenses.

In November 2019, we completed an underwritten public offering of an aggregate of (i) 103,000 shares of Series A Preferred Stock, that all converted into 7,803,273 shares of common stock in January 2020, (ii) Series A warrants to purchase up to an aggregate of 7,802,241 shares of our common stock at an exercise price equal to \$13.20, and (iii) Series B warrants to purchase up to an aggregate of 2,574,727 shares of common stock at an exercise price equal to \$13.20. Each share of Series A Preferred Stock and the accompanying Series A and Series B warrants were issued at a combined price to the public of \$1,000. The aggregate net proceeds received by us from the offering were \$97.7 million, net of underwriting discounts and commissions and offering expenses. The Series B warrants may only be exercised by paying the exercise price in cash, and if fully exercised would amount to approximately \$34.0 million in proceeds to us.

In August 2018, we entered into a Loan and Security Agreement (Loan Agreement) with Silicon Valley Bank (SVB), pursuant to which we could obtain a loan of aggregate principal amount of up to \$15.0 million. In 2018, we borrowed \$5.0 million under the first tranche, which bore interest at the greater of 6.0% or a floating per annum rate 1.0% above the prime rate. In December 2019, we repaid the loan in full.

We expect to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- invest to further develop our lead product candidate, momelotinib;
- hire additional clinical, scientific, drug development and management personnel, as well as personnel to support any future commercialization efforts;

- invest in scaling our manufacturing capacity to support development and our global commercialization strategy;
- seek regulatory and marketing approvals for any product candidates that we may develop;
- · achieve regulatory milestones that trigger payments due under our Asset Purchase Agreement with Gilead;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any drugs for which we may obtain marketing approval;
- acquire or in-license additional product candidates and technologies;
- develop additional product candidates;
- defend against potential lawsuits or other legal issues;
- maintain, expand and protect our intellectual property portfolio; and
- add operational, financial and management information systems and personnel to continue to operate as a public company.

To fund our current operating plans, we will need to raise additional capital. Our existing cash and cash equivalents will not be sufficient for us to complete development and prepare for commercializing momelotinib. Accordingly, we will continue to require substantial additional capital to continue our clinical development and potential commercialization activities; however, we believe that our existing cash and cash equivalents will be sufficient to fund our current operating plans into the second half of 2022. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities. However, our forecast for the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our preclinical and clinical development efforts.

We plan to continue to fund our current operating plans' needs through equity financings or other arrangements. To the extent that we raise additional capital through future equity financings, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through the issuance of debt securities, these securities could contain covenants that would restrict our operations. There can be no assurance that such additional financing, if available, can be obtained on terms acceptable to us. If we are unable to obtain such additional financing, we would need to reevaluate our future operating plans. We intend to seek non-dilutive strategic options to support the continued development of SRA737 and SRA141 in the future. There can be no assurance that we will successfully obtain non-dilutive development support or obtain the funding or support necessary to advance SRA737 or SRA141 or obtain such funding or support on commercially reasonable terms.

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

	Year E	
	Decemb	
	2019	2018
	(in thou	sands)
Cash used in operating activities	\$(51,183)	\$(45,115)
Cash used in investing activities	(39)	(118)
Cash provided by financing activities	92,738	51,131
Effect of foreign exchange rate changes on cash, cash equivalents and restricted		
cash	(34)	(88)
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 41,482	\$ 5,810

# Cash Flows from Operating Activities

In 2019, cash used in operating activities of \$51.2 million was attributable to a net loss of \$88.3 million and a net change of \$2.0 million in our net operating assets and liabilities, partially offset by \$39.1 million in non-cash and other adjustments. The non-cash and other adjustments consisted primarily of a \$20.9 million change in fair value of our warrant liabilities, a \$10.5 million non-cash expense relating to the securities issuable to Gilead in connection with the amendment to the Asset Purchase Agreement, \$5.7 million of non-cash stock-based compensation, and a \$1.7 million reclassification of cash flows, pertaining to the issuance of warrants and repayment of debt, to financing activities. The change in net operating assets and liabilities was primarily attributable to a decrease in our accrued and other liabilities and operating lease liabilities.

In 2018, cash used in operating activities of \$45.1 million was attributable to a net loss of \$53.3 million, partially offset by \$6.8 million in non-cash charges and a net change of \$1.4 million in our net operating assets and liabilities. The non-cash charges consisted primarily of \$6.8 million in stock-based compensation.

## Cash Flows from Investing Activities

Cash used in investing activities for each of December 31, 2019 and 2018 was primarily attributable to the purchase of property and equipment.

## Cash Flows from Financing Activities

In 2019, cash provided by financing activities was \$92.7 million, attributable to net proceeds of \$97.7 million received from our November 2019 financing and \$0.4 million of proceeds received from the exercise of options to purchase common stock, partially offset by a \$5.4 million payment to settle our term loan and related repayment obligations.

In 2018, cash provided by financing activities was \$51.1 million, attributable to net proceeds of \$46.0 million received from the sale and issuance of our common stock upon our follow-on offering, \$5.0 million of proceeds received from borrowing under the Loan Agreement and \$0.2 million of proceeds received from the exercise of options to purchase common stock.

# **Contractual Obligations and Other Commitments**

The following table summarizes our contractual obligations as of December 31, 2019, which represent material expected or contractually committed future obligations.

	Payments Due By Period				 	
	Total	Less Than 1 Year	1 to 3 Years	3 to	5 Years	re Than Years
			(in thousands)			
Purchase commitments(1)	\$22,573	\$ 9,891	\$ 11,953	\$	729	\$ _
Operating lease obligations(2)	615	217	398			
Total contractual obligations	\$23,188	\$ 10,108	\$ 12,351	\$	729	\$ 

<sup>(1)</sup> Reflects payments we are required to make pursuant to clinical trial and manufacturing agreements.

Under the terms of the agreements with Gilead, CRT Pioneer Fund LP (CPF) and Carna, we will be required to pay future milestones if certain developmental, regulatory and commercial milestones are achieved. Future milestones for which we cannot reliably estimate the timing have been excluded from the table above.

<sup>(2)</sup> Reflects payments we are required to make under operating lease agreements. Costs such as taxes and other operating costs are not included in the amounts disclosed. (See Note 6 to the financial statements under Item 8 of this Form 10-K.)

## **Critical Accounting Policies and Estimates**

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

## Research and Development Expenses

As part of the process of preparing financial statements, we are required to estimate and accrue expenses, a significant portion of which are research and development expenses. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites. This process involves the following:

- reviewing quotations and contracts, identifying services that have been performed on our behalf and estimating the level of service
  performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost;
- estimating and accruing expenses in our financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and
- periodically confirming the accuracy of our estimates with selected service providers and making adjustments, if necessary.

Estimated research and development expenses that we accrue include clinical trial costs under arrangements with third parties, such as contract research organizations (CROs), manufacturing costs under agreements with contract manufacturing organizations (CMOs), external research and development expenses incurred under arrangement with third parties and consultants, and license fees for technology that has not reached technological feasibility and does not have an alternative future use.

We base our expense accruals related to clinical trials on patient enrollment and our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions that conduct and manage clinical trials on our behalf. The financial terms of these agreements vary for each contract and may result in uneven payment flows. Payments under some of these contracts depend on several factors, such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. For service contracts entered into that include a nonrefundable prepayment for service, the upfront payment is deferred and recognized in the statement of operations as the services are rendered.

Contingent milestone payment obligations due to third parties under license and asset purchase agreements are expensed when the milestones are considered probable of occurring. To the extent that an obligation is to be settled by future issuance of securities, the fair value of the instruments is recorded in research and development expense until the securities are issued.

To date, we have not experienced significant changes in our estimates of accrued research and development expenses after a reporting period. However, due to the nature of estimates, we cannot assure you that we will not

make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials and other research activities

# Stock-Based Compensation

Stock-based compensation costs related to stock options granted to employees are measured at the date of grant based on the estimated fair value of the award. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. The fair value of any options issued to non-employees is recorded as expense over the vesting period, which is generally the service period.

On January 1, 2019, we adopted FASB ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which aligns the guidance for share-based payments issued for goods and services for employees and nonemployees. The adoption of this new accounting guidance did not have a material impact on our consolidated financial statements.

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

Expected Term—The expected term represents the period that stock-based awards are expected to be outstanding. As our historical share option exercise is limited due to a lack of sufficient data points, and does not provide a reasonable basis upon which to estimate an expected term, we estimate the expected term by using the midpoint between the vesting commencement date and the contractual expiration period of the stock-based award.

*Expected Volatility*—Since we have limited information on the volatility of common stock due to its short trading history, the expected volatility is derived from the historical stock volatilities of comparable peer public companies within our industry that are considered to be comparable to our business over a period equivalent to the expected term of the stock-based awards.

*Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the stock-based awards' expected term.

*Expected Dividend Rate*—The expected dividend is zero as we have not paid nor anticipate paying any dividends on our common stock in the foreseeable future.

Forfeiture Rate—We account for forfeitures when they occur.

We will continue to use judgment in evaluating the expected volatility and expected terms utilized for our stock-based compensation calculations on a prospective basis.

# **Warrant Liabilities**

Warrants for the purchase of shares of our common stock issued in connection with our November 2019 financing are classified as derivative liabilities on our consolidated balance sheets at their fair value on the date of issuance. At the end of each reporting period, changes in estimated fair value during the period are recognized as a component of other income (expense), net in our statement of operations. We will continue to adjust the carrying value of the warrants until such time as the warrants are no longer considered derivative instruments, or until the earlier of the exercise of the warrants or the expiration of the warrants, at which time the liabilities will be reclassified to additional paid-in capital at their fair value.

We estimate the fair value of these liabilities using assumptions that are based on the individual characteristics of the warrants on the valuation date. We use the Black-Scholes option-pricing model and the fair value of the

underlying stock to determine the fair value of these liabilities. The valuation model is based on inputs as of the valuation dates, including the estimated volatility of our stock, the remaining contractual term of the warrants and the risk-free interest rates. An estimated non-marketable discount is also applied.

## Securities Issuance Obligation

The obligation to issue shares of our common stock and a warrant to purchase the same number of shares of common stock pursuant to the amendment to the Asset Purchase Agreement with Gilead is classified as a liability on our consolidated balance sheet at their fair values on the date such obligations arose. At the end of each reporting period, changes in estimated fair values during the period are recognized as research and development expense on our statement of operations. We will continue to adjust the fair values of the obligations until the securities are issued, at which time the liabilities will be reclassified to common stock and additional paid-in capital at their fair values.

On the valuation date, we estimate the fair values of these obligations using assumptions that are based on the individual characteristics of the securities to be issued. We use the fair value of the underlying stock and estimated non-marketable discount to determine the common stock issuance obligation, and the Black-Scholes option-pricing model and the fair value of the underlying stock to determine the fair value of the warrant issuance obligation. The valuation model is based on inputs as of the valuation dates, including the estimated volatility of our stock, the remaining contractual term of the warrants and the risk-free interest rates. An estimated non-marketable discount is also applied.

#### **Off-Balance Sheet Arrangements**

As of December 31, 2019, we did not have any off-balance sheet financing arrangements or any interest in entities referred to as variable interest entities, which includes special purpose entities and other structured finance entities.

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

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities and foreign currency risk.

## **Interest Rate Sensitivity**

We had cash and cash equivalents of \$147.5 million as of December 31, 2019, which consisted primarily of bank deposits and money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our consolidated financial condition or results of operations. We do not believe that our cash or cash equivalents have significant risk of default or illiquidity.

## Foreign Currency Risk

Our consolidated results of operations and cash flows are subject to fluctuations due to changes in foreign currency exchange rates. A substantial majority of our expenses are denominated in U.S. Dollars, with the remainder in Canadian Dollars, British Pounds and Australian Dollars. Our consolidated results of operations and cash flow are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. To date, we have not entered into any hedging arrangements with respect to foreign currency risk or other derivative instruments. The effect of a hypothetical 10% change in foreign currency exchanges rates applicable to our business would not have a material impact on our operating loss.

# Item 8. Consolidated Financial Statements and Supplementary Data.

# INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
SIERRA ONCOLOGY, INC.	<u>a-</u>
Report of Independent Registered Public Accounting Firm	91
Consolidated Balance Sheets	92
Consolidated Statements of Operations and Comprehensive Loss	93
Consolidated Statements of Stockholders' Equity	94
Consolidated Statements of Cash Flows	95
Notes to Consolidated Financial Statements	96

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Sierra Oncology, Inc.: Vancouver, British Columbia, Canada

# **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Sierra Oncology Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows, for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

## **Basis for Opinion**

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

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

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

/s/ Deloitte & Touche LLP

Grand Rapids, Michigan March 3, 2020

We have served as the Company's auditor since 2014.

# Consolidated Balance Sheets (in thousands, except share and per share data)

ASSETS		2018
CURRENT ASSETS:		
Cash and cash equivalents	\$ 147,528	\$ 106,046
Prepaid expenses and other current assets	2,369	2,706
Total current assets	149,897	108,752
Property and equipment, net	113	168
Operating lease right-of-use asset	589	_
Other assets	729	549
TOTAL ASSETS	\$ 151,328	\$ 109,469
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accrued and other liabilities	\$ 7,170	\$ 8,812
Accounts payable	1,019	1,287
Warrant liabilities	45,935	_
Securities issuance obligation	10,485	
Total current liabilities	64,609	10,099
Operating lease liability	374	_
Term loan		4,891
TOTAL LIABILITIES	64,983	14,990
Commitments and Contingencies (Note 8)		
STOCKHOLDERS' EQUITY:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized as of December 31, 2019 and December 31, 2018;		
103,000 shares Series A convertible voting preferred stock, issued and outstanding as of December 31, 2019 and nil		
shares issued and outstanding as of December 31, 2018	1	_
Common stock, \$0.001 par value; 500,000,000 shares authorized as of December 31, 2019 and 2018; 1,867,176 and		
1,859,120 shares issued and outstanding as of December 31, 2019 and 2018	74	74
Additional paid-in capital	851,957	771,817
Accumulated deficit	(765,687)	(677,412)
TOTAL STOCKHOLDERS' EQUITY	86,345	94,479
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 151,328	\$ 109,469

# SIERRA ONCOLOGY, INC.

# Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share data)

		Year Ended December 31,	
	2019	2018	2017
Operating expenses:			
Research and development	\$ 53,249	\$ 41,078	\$ 30,157
General and administrative	13,743	14,339	12,462
Total operating expenses	66,992	55,417	42,619
Loss from operations	(66,992)	(55,417)	(42,619)
Other income (expense), net:			
Changes in fair value of warrant liabilities	(20,926)	_	_
Other income (expense), net	(517)	1,780	760
Total other income (expense)	(21,443)	1,780	760
Loss before provision for (benefit from) income taxes, net	(88,435)	(53,637)	(41,859)
Provision for (benefit from) income taxes, net	(160)	(302)	156
Net loss and comprehensive loss	(88,275)	(53,335)	(42,015)
Net loss per common share, basic and diluted	\$ (30.30)	\$ (30.16)	\$ (33.68)
Weighted-average shares used in computing net loss per common share, basic and diluted	2,913,487	1,768,480	1,247,482

# SIERRA ONCOLOGY, INC.

# Consolidated Statements of Stockholders' Equity (in thousands, except share data)

Series A Convertible Voting Preferred Stock Additional Total **Common Stock** Accumulated Stockholders' Paid-In Capital Shares Amount Shares Amount Deficit Equity Balance—December 31, 2016 759,253 103,248 30 \$685,272 \$ (582,054) Issuance of common stock for exercise of stock options 4,413 166 166 Cumulative effect of adoption of new accounting standard 8 (8) Stock-based compensation 5,905 5,905 Issuance of common stock, net of offering costs of \$2.1 million 546,190 22 27,400 27,422 (42,015)Net loss (42,015)52 Balance—December 31, 2017 1,309,856 718,751 (624,077)94,726 Issuance of common stock for exercise of stock options 3,014 180 180 Stock-based compensation 6,796 6,796 Issuance of common stock, net of offering costs of \$3.2 million 546,250 22 45,974 45,996 Issuance of common stock warrant 116 116 Net loss (53,335)(53,335)1,859,120 74 Balance—December 31, 2018 771,817 (677,412)94,479 Issuance of common stock for exercise of stock options 8,056 445 445 Stock-based compensation 5,695 5,695 Issuance of convertible voting preferred stock, net of offering costs of \$4.0 million 103,000 74,000 74,001 1 Net loss (88,275)(88,275)1,867,176 Balance—December 31, 2019 103,000 74 \$851,957 \$ (765,687) 86,345 1

# Consolidated Statements of Cash Flows (in thousands)

	Year Ended December 31,		
CACH DI ONE EDOM ODED ATTINE A CHIMITIE	2019	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:	<b>ተ (00 275)</b>	<b>ታ (</b> ED 22E)	¢ (42.015)
Net loss	\$ (88,275)	\$ (53,335)	\$ (42,015)
Adjustments to reconcile net loss to net cash used in operating activities:	20.026		
Changes in fair value of warrant liabilities	20,926		
Securities issuance obligation	10,485	— C 700	
Stock-based compensation	5,695	6,796	5,905
Warrant issuance costs	1,279	_	_
Term loan repayment fee	438		
Depreciation and amortization	83	111	258
Other	161	(68)	31
Changes in operating assets and liabilities:	22.6	(4.0.44)	(445)
Prepaid expenses and other assets	336	(1,341)	(115)
Accrued, other and operating lease liabilities	(2,034)	2,770	990
Accounts payable	(277)	(48)	(1,217)
Net cash used in operating activities	(51,183)	(45,115)	(36,163)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(39)	(118)	(92)
Net cash used in investing activities	(39)	(118)	(92)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from public offering, net of offering costs	97,731	_	
Payment of term loan and repayment fee	(5,438)	_	_
Proceeds from exercise of common stock options	445	180	166
Proceeds from issuance of common stock upon follow-on offering, net of offering costs	_	45,996	27,422
Proceeds from issuance of term loan, net of issuance costs	_	4,955	_
Net cash provided by financing activities	92,738	51,131	27,588
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(34)	(88)	(4)
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	41,482	5,810	(8,671)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH—Beginning of period	106,346	100,536	109,207
CASH, CASH EQUIVALENTS AND RESTRICTED CASH—End of period	\$147,828	\$106,346	\$100,536
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash paid for (refund of) income taxes, net	\$ (69)	\$ 15	\$ 260
Cash paid for interest	\$ 336	\$ 87	\$ —
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING	<u> </u>	<u> </u>	
INFORMATION:			
Right-of-use asset obtained in exchange for operating lease obligation	\$ 771	\$ —	s —
Issuance costs of convertible voting preferred stock and warrants included in accrued and other liabilities	\$ 268		\$ —
	\$	<u>\$ —</u> \$ 116	ф
Issuance of common stock warrant	<u> </u>	<u>\$ 116</u>	<u> </u>

## **Notes to Consolidated Financial Statements**

# 1. The Company and Basis of Presentation

## **Organization and Description of Business**

Sierra Oncology, Inc. (together with its subsidiaries, collectively referred to as the "Company"), a Delaware corporation, is a late stage drug development company focused on advancing its lead product candidate, momelotinib, a potent, selective and orally-bioavailable JAK1 (Janus kinase 1), JAK2 (Janus kinase 2) and ACVR1 (Activin A receptor type 1) inhibitor with a potentially differentiated therapeutic profile for the treatment of myelofibrosis. Momelotinib has been investigated in two completed Phase 3 clinical trials for the treatment of myelofibrosis and has demonstrated a potentially differentiated therapeutic profile encompassing anemia-related clinical benefits, as well as achieving constitutional symptom control benefits and substantive splenic volume reductions. The Company's portfolio also includes two DNA Damage Response (DDR) assets, consisting of SRA737 and SRA141. SRA737 is a potent, highly selective, orally bioavailable small molecule inhibitor of Checkpoint kinase 1 (Chk1), a key regulator of cell cycle progression and the DDR network. SRA141 is a potent, selective and orally bioavailable small molecule inhibitor of Cell division cycle 7 kinase (Cdc7), a key regulator of DNA replication and involved in the DDR network.

The Company's primary activities since inception have been conducting research and development activities, conducting preclinical and clinical testing, recruiting personnel, performing business and financial planning, identifying and evaluating additional drug candidates for potential in-licensing or acquisition, and raising capital to support development activities.

The Company has not generated any product revenue related to its primary business purpose to date, nor has it generated any income, and is subject to a number of risks and uncertainties, which include dependence on key individuals, the need to identify and successfully develop commercially viable products, the need to obtain regulatory approval for its products and commercialize them, and the need to obtain adequate additional financing to fund the development of its product candidates.

As of December 31, 2019, the Company had \$147.5 million of cash and cash equivalents. The Company believes that its balance of cash and cash equivalents as of the date of the issuance of these consolidated financial statements is sufficient to fund its current operational plan for at least the next twelve months though it may pursue raising additional capital through equity financings or other arrangements.

## **Follow-On Offerings**

On February 14, 2017, the Company completed an underwritten public offering of 487,500 shares of common stock. As part of the underwritten public offering, on February 21, 2017 the Company issued an additional 58,690 shares of common stock representing the underwriters' exercise of a majority of their over-allotment option. All shares were offered by the Company at a price to the public of \$54.00 per share. The aggregate net proceeds received by the Company from the offering were \$27.4 million, net of underwriting discounts and commissions and offering expenses of \$2.1 million.

On March 6, 2018, the Company completed an underwritten public offering of an aggregate of 546,250 shares of common stock, including the underwriters' exercise of their overallotment option, at a price to the public of \$90.00 per share. The aggregate net proceeds received by the Company from the offering were \$46.0 million, net of underwriting discounts and commissions and offering expenses of \$3.2 million.

On November 13, 2019, the Company completed an underwritten public offering of an aggregate of (i) 103,000 shares of Series A convertible voting preferred stock (Series A Preferred Stock), (ii) Series A warrants to purchase up to an aggregate of 7,802,241 shares of common stock at an exercise price equal to \$13.20, and (iii) Series B warrants to purchase up to an aggregate of 2,574,727 shares of common stock at

## SIERRA ONCOLOGY, INC.

## **Notes to Consolidated Financial Statements**

an exercise price equal to \$13.20. Each share of Series A Preferred Stock and the accompanying Series A and Series B warrants were issued at a combined purchase price to the public of \$1,000. The aggregate net proceeds received by the Company from the offering were \$97.7 million, net of underwriting discounts and commissions and offering expenses of \$5.3 million. On January 29, 2020, all shares of Series A Preferred Stock converted into 7,803,273 shares of common stock.

## **Reverse Stock Split**

On January 21, 2020, the Company's shareholders approved an amendment to the Company's certificate of incorporation to effect a reverse split of the Company's common stock (Reverse Stock Split). On January 21, 2020, the Company's board of directors approved the specific ratio for the Reverse Stock Split, which became effective on January 22, 2020, at 1-for-40. The authorized shares and par value of the common and preferred stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock, warrants for common stock, options for common stock and per share amounts contained in the consolidated financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented.

# 2. Summary of Significant Accounting Policies

## **Basis of Presentation**

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP). The accompanying consolidated financial statements include the accounts of Sierra Oncology, Inc. and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

## **Use of Estimates**

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of consolidated financial statements and the reported amounts of expense during the reporting period. Significant estimates and assumptions made in the accompanying consolidated financial statements include, but are not limited to the fair value of convertible voting preferred stock, stock options and warrants issued, fair value of the securities issuance obligation, accruals such as research and development costs, and recoverability of the Company's net deferred tax assets, and related valuation allowance. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

# **Foreign Currency**

The functional currency of the Company's foreign subsidiaries is the U.S. Dollar. Transactions denominated in currencies other than the functional currency are recorded at prevailing exchange rates during the period. At the end of each reporting period, monetary assets and liabilities are remeasured to the functional currency using exchange rates in effect at the balance sheet date. Non-monetary assets and liabilities are recorded at historical exchange rates. Gains and losses related to remeasurement are recorded in other income (expense), net in the consolidated statements of operations. The net foreign exchange transaction gains (losses) included in other income (expense), net in the accompanying consolidated statements of operations were insignificant for the years ended December 31, 2019, 2018 and 2017.

## **Notes to Consolidated Financial Statements**

# **Cash and Cash Equivalents**

The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents. Cash and cash equivalents consist primarily of funds invested in readily available checking and savings accounts and highly liquid investments in money market funds.

# **Restricted Cash**

Restricted cash, which consists of funds invested in a money market fund, represents collateral for a corporate credit card facility and is included in other assets in the accompanying consolidated balance sheets.

# **Concentrations of Credit Risk**

Financial instruments that subject the Company to significant concentrations of credit risk consist of cash, cash equivalents and restricted cash. All of the Company's cash, cash equivalents and restricted cash are held at financial institutions in the United States and Canada that management believes to be of high credit quality. Deposits held in the United States and Canada with these financial institutions exceed federally insured limits.

The primary focus of the Company's investment strategy is to preserve capital and meet liquidity requirements. The Company's investment policy addresses the level of credit exposure by limiting the concentration in any one corporate issuer and establishing a minimum allowable credit rating.

#### Fair Value of Financial Instruments

The Company's cash and cash equivalents, restricted cash, other current assets, accounts payable and accrued liabilities approximate their fair values at December 31, 2019 and 2018, due to their short duration. Prior to its repayment in December 2019, the term loan bore interest at prevailing market rates for instruments with similar characteristics, accordingly, the carrying value of this instrument approximated its fair value. The warrant liabilities and securities issuance obligation contain unobservable inputs that reflect the Company's own assumptions in which there is little, if any, market activity at the measurement date, thus the Company's warrant liabilities and securities issuance obligation are measured at their fair values on a recurring basis using unobservable inputs.

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines the fair value of its financial instruments based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

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

## **Notes to Consolidated Financial Statements**

# Property and Equipment, Net

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

# Other Assets

Other assets consist primarily of restricted cash pledged as collateral for a corporate credit card facility and deferred income tax assets in foreign jurisdictions.

# Operating Lease Right-of-Use Asset and Lease Liability

On January 1, 2019, the Company adopted Financial Accounting Standards Board (FASB) Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842)* on a modified retrospective basis and did not restate comparative periods as permitted under the transition guidance. The Company elected the package of practical expedients as permitted, which carries forward the Company's assessments prior to the date of initial application with respect to lease classifications, initial direct costs as well as whether an existing contract contains a lease. The Company also elected to account for lease and non-lease components separately under transition relief available.

The Company recognizes an operating lease with terms greater than one year as right-of-use (ROU) asset and lease liability on its consolidated balance sheet using the portfolio approach. Lease liability and ROU asset are recorded based on the present value of future lease payments over the contractual term of the operating lease. The Company utilized its incremental borrowing rate from information available as at the date of initial adoption in determining the present value of the future lease payments. The lease liability and ROU asset are amortized over the term of the lease with operating lease expense being recognized on a straight-line basis over the lease term.

#### **Warrant Liabilities**

The Company accounts for its warrants issued in connection with its November 2019 financing based upon the characteristics and provisions of the instruments. Warrants classified as derivative liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and remeasured to fair value on each subsequent reporting period, with the changes in fair value recognized as a component of other income (expense), net in the accompanying consolidated statements of operations. The Company will continue to adjust the carrying value of the warrants until such time as the warrants are no longer considered derivative instruments, or until the earlier of the exercise of the warrants or the expiration of the warrants, at which time the liabilities will be reclassified to additional paid-in capital at their fair value. The Company estimates the fair value of these liabilities using the Black-Scholes option-pricing model and the fair value of the underlying stock, as well as assumptions for expected volatility, expected term and risk-free interest rate. An estimated non-marketable discount is also applied. Offering expenses arising from the issuance of warrants are expensed as incurred.

## **Notes to Consolidated Financial Statements**

# **Securities Issuance Obligation**

The Company recognizes its securities issuance obligation pursuant to the amendment to the Asset Purchase Agreement with Gilead Sciences, Inc. (Gilead) at their fair values on the date such obligations arose. At the end of each reporting period, changes in estimated fair values during the period are recognized as research and development costs in the accompanying consolidated statements of operations. The Company will continue to adjust the fair values of the obligations until the securities are issued, at which time the liabilities will be reclassified to common stock and additional paid-in capital at their fair values. The Company determines the fair values of these obligations based upon the individual characteristics and provisions of the securities to be issued. The Company estimates the fair value of its obligation to issue common stock using the fair value of the underlying stock and a non-marketable discount. The Company estimates the fair value of its obligation to issue warrant using the Black-Scholes option-pricing model and the fair value of the underlying stock, as well as assumptions for expected volatility, expected term and risk-free interest rate. An estimated non-marketable discount is also applied.

# **Research and Development Costs**

Research and development costs are expensed as incurred. The Company accounts for non-refundable advance payments for goods and services that will be used in future research and development activities as expenses when the goods have been received or when the service has been performed rather than when the payment is made. Depending on the timing of payments to service providers of research and development costs, the Company recognizes prepaid expenses or accrued expenses related to these costs. These prepaid or accrued expenses are based on management's estimates of the work performed under service agreements and milestones achieved. In the event that a clinical trial is terminated early, the Company records an accrual for the estimated remaining costs to complete the trial in the period of termination.

Upfront payments made in connection with license and asset purchase agreements are expensed as research and developments costs, as the assets acquired do not have alternative future use. Contingent milestone payment obligations due to third parties under license and asset purchase agreements are expensed when the milestones are considered probable of occurring. To the extent an obligation is to be settled by future issuance of securities, the fair value of these instruments is recorded in research and development expense until the securities are issued.

Research and development costs include fees incurred in connection with license and asset purchase agreements and their related amendments, compensation and other related costs for employees engaged in research and development, costs associated with research and preclinical studies, clinical trials, regulatory activities, manufacturing activities to support clinical activities, fees paid to external service providers that conduct certain research and development, clinical, and manufacturing activities on behalf of the Company and an allocation of overhead expenses.

# **Stock-Based Compensation**

The Company accounts for stock-based payments at fair value, which is measured using the Black-Scholes option-pricing model. For stock-based awards that vest subject to the satisfaction of a service requirement, the fair value measurement date for stock-based compensation awards is the date of grant and the expense is recognized on a straight-line basis over the vesting period, which is generally the service period. The Company accounts for forfeitures as they occur.

On January 1, 2019, the Company adopted FASB ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which aligns the guidance

## SIERRA ONCOLOGY, INC.

## **Notes to Consolidated Financial Statements**

for share-based payments issued for goods and services for employees and nonemployees. The adoption of this new accounting guidance did not have a material impact on the Company's consolidated financial statements.

#### **Income Taxes**

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Management makes an assessment of the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's historical operating performance and the recorded cumulative net losses in prior fiscal periods, the net U.S. deferred tax assets have been offset by a full valuation allowance.

The Company recognizes uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Changes in recognition or measurement are reflected in the period in which judgment occurs. The Company recognizes interest and penalties related to the underpayment of income taxes as a component of provision for (benefit from) income taxes, net.

# **Segment Information**

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company's chief operating decision maker in deciding how to allocate resources and assessing performance. The Company's chief operating decision maker is its Chief Executive Officer.

The Company's Chief Executive Officer views the Company's operations and manages its business in one operating segment, which is the business of researching, developing and commercializing therapies for the treatment of patients with hematology and oncology needs. Accordingly, the Company has a single reporting segment.

## 3. Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common stock and preferred stock with characteristics of common stock outstanding during the period without consideration for common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, stock options and warrants for common stock are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

# **Notes to Consolidated Financial Statements**

The following shares of common stock equivalents were excluded from the calculation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	As of December 31,				
	2019	2018	2017		
Series A warrants for common stock	7,802,241	_	_		
Series B warrants for common stock	2,574,727	_	_		
Stock options to purchase common stock	326,023	262,539	186,710		
Warrant for common stock	1,839	1,839			
Total potential dilutive shares	10,704,830	264,378	186,710		

## 4. Fair Value Measurements

The Company measures and reports its cash equivalents, restricted cash, warrant liabilities and securities issuance obligation at fair value. The following table sets forth the fair value of the Company's financial assets and liabilities measured on a recurring basis by level within the fair value hierarchy:

		December 31, 2019		
	Level 1	Level 2	Level 3	Total
		(in tho	usands)	
Financial Assets				
Money market funds	\$146,240	\$ —	\$ —	\$146,240
Restricted money market funds	300	_	_	300
Total financial assets	\$146,540	\$ —	\$ —	\$146,540
Financial Liabilities				
Warrant liabilities	\$ —	\$ —	\$45,935	\$ 45,935
Securities issuance obligation	<del>-</del>	_	10,485	10,485
Total financial liabilities	<u> </u>	<u>\$ —</u>	\$56,420	\$ 56,420
		Decemb	per 31, 2018	
	Level 1	Level 2	Level 3	Total
		(in th	ousands)	

		December 31, 2010		
	Level 1	Level 2	Level 3	Total
	·	(in tho	usands)	
Financial Assets				
Money market funds	\$105,224	\$ —	\$ —	\$105,224
Restricted money market funds	300	_	_	300
Total financial assets	\$105,524	<u>\$ —</u>	<u>\$ —</u>	\$105,524

Money market funds and restricted money market funds are measured at fair value on a recurring basis using quoted prices and are classified as a Level 1 input.

The Company's warrant liabilities and securities issuance obligation contain unobservable inputs that reflected the Company's own assumptions in which there is little, if any, market activity at the measurement date. Accordingly, the Company's warrant liabilities and securities issuance obligation are measured at fair value on a recurring basis using unobservable inputs at each reporting period. The warrant liabilities and securities issuance obligation are classified as Level 3 inputs. These liabilities are shown as current liabilities on the balance sheet as they are deemed more probable than not by management to be settled within one year.

## **Notes to Consolidated Financial Statements**

The fair values of the Series A and Series B warrants are estimated using the Black-Scholes option-pricing model. The expected terms represent the periods that the warrants are expected to be outstanding. The risk-free interest rates are based on the U.S. Constant Maturity treasury curve commensurate with the time to expiry. The expected dividend is zero as the Company has not paid nor does it anticipate paying any dividends on its common stock in the foreseeable future. The expected volatilities are estimated by backsolving to volatility implied in the transaction price. Discount for lack of marketability is dependent on the restriction period and the estimated volatility during the period.

The fair value of the warrant issuance obligation is estimated using the Black-Scholes option-pricing model. The expected term represents the period that the underlying warrant is expected to be outstanding from the time the issuance obligation arose. The risk-free interest rate is based on the U.S. Constant Maturity treasury curve commensurate with the time to expiry. The expected dividend is zero as the Company has not paid nor does it anticipate paying any dividends on its common stock in the foreseeable future. The expected volatility is estimated by backsolving to volatility implied in the transaction price. The fair value of the common stock issuance obligation is estimated based on the fair value of the underlying common stock. Discount for lack of marketability is dependent on the restriction period and the estimated volatility during the period.

The assumptions used in calculating the estimated fair values at the end of the reporting period represent the Company's best estimate. However, inherent uncertainties are involved. If factors or assumptions change, the estimated fair values could be materially different.

At November 13, 2019, the Company estimated the fair values of the financial liabilities using the following assumptions:

	Series A Warrant	Series B Warrant	Warrant Issuance Obligation	Common Stock Issuance Obligation
Expected term (in years)	5.2	2.3	5.2	N/A
Expected volatility	43%	88%	43%	N/A
Risk-free interest rate	1.70%	1.64%	1.70%	N/A
Expected dividend yield	— %	— %	— %	N/A
Discount for lack of marketability	30%	30%	32%	32%

At December 31, 2019, the Company remeasured these liabilities to their fair values using the following assumptions:

	Series A Warrant	Series B Warrant	Warrant Issuance Obligation	Common Stock Issuance Obligation
Expected term (in years)	5.1	2.2	5.1	N/A
Expected volatility	43%	88%	43%	N/A
Risk-free interest rate	1.69%	1.59%	1.70%	N/A
Expected dividend yield	— %	— %	— %	N/A
Discount for lack of marketability	25%	25%	25%	25%

# **Notes to Consolidated Financial Statements**

The following table provides a summary of changes in the estimated fair values of the Company's Level 3 financial liabilities, which are measured at fair value on a recurring basis using unobservable inputs:

	Series A Warrant <u>L</u> iability	Series B Warrant Liability	Warrant Issuance Obligation (in thousand	Common Stock Issuance Obligation	Total
Balance, December 31, 2018	\$ —	\$ —	\$ —	* —	\$ —
Issuance of warrants	17,133	7,876	_	_	25,009
Securities issuance obligation			1,543	4,903	6,446
Changes in fair value	15,483	5,443	1,493	2,546	24,965
Balance, December 31, 2019	\$32,616	\$13,319	\$ 3,036	\$ 7,449	\$56,420

The warrant liabilities will increase or decrease each reporting period based on fluctuations of the fair value of the underlying common stock until such time these financial liabilities are no longer considered derivative instruments, or the earlier of settlement and expiration of warrants. The change in the fair value of warrant liabilities for each presented period is recognized as a component of other income (expense), net in the consolidated statements of operations.

The securities issuance obligation will increase or decrease each reporting period based on fluctuations of the fair value of the underlying common stock until such time the securities are issued. The change in fair values of securities issuance obligation is recognized as research and development expense in the consolidated statement of operations.

There were no transfers between Levels 1, 2 or 3 during the years ended December 31, 2019 and 2018.

## 5. Balance Sheet Components

# **Cash and Cash Equivalents**

Cash and cash equivalents consist of the following:

	Dece	mber 31,
	2019	2018
	(in th	ousands)
Cash	\$ 1,288	\$ 822
Cash equivalents:		
Money market accounts	146,240	105,224
Total cash and cash equivalents	\$147,528	\$106,046

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported in the consolidated balance sheets to the amounts shown in the consolidated statements of cash flows.

	De	cember 31, 2019	De	ecember 31, 2018
		(in th	ousands)	
Cash and cash equivalents	\$	147,528	\$	106,046
Restricted cash included in other assets	_	300		300
Total cash, cash equivalents and restricted cash shown in the consolidated				
statement of cash flows	\$	147,828	\$	106,346

# **Notes to Consolidated Financial Statements**

# **Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consist of the following:

	December 31,	
	2019	2018
	(in tho	usands)
Prepaid insurance	\$ 918	\$ 555
Prepaid research and development project costs	853	762
Other receivables	190	751
Income taxes receivable	7	163
Other	401	475
Total prepaid expenses and other current assets	\$2,369	\$2,706

# Property and Equipment, net

Property and equipment, net consists of the following:

	Dec	ember 31,
	2019	2018
	(in t	housands)
Software	\$ 352	\$ 325
Leasehold improvements	112	112
Computer equipment	89	89
Furniture and fixtures	3	3
Property and equipment, gross	556	529
Less: accumulated depreciation	(443)	(361)
Total property and equipment, net	\$ 113	\$ 168

Depreciation related to the Company's property and equipment for the years ended December 31, 2019, 2018 and 2017 was \$0.1 million, \$0.1 million and \$0.3 million, respectively.

# **Accrued Liabilities**

Accrued liabilities consist of the following:

	Decer	mber 31,
	2019	2018
	(in the	ousands)
Accrued employee related costs	\$3,420	\$3,223
Accrued research and development costs	2,668	4,485
Accrued professional fees	817	357
Operating lease liability	187	_
Other	78	747
Total accrued liabilities	\$7,170	\$8,812

# **Notes to Consolidated Financial Statements**

#### 6. Leases

In June 2017, the Company entered into an operating lease agreement to lease the office space in Vancouver, Canada commencing March 1, 2018. The lease expires on February 28, 2023 and can be extended for an additional term of 5 years.

In January 2016, the Company entered into an operating lease agreement to lease office space near San Francisco, California. In September 2017, the Company entered into a sublease agreement to sublet the premises to a third party. Both the operating lease and sublease agreements expired on April 30, 2019.

On January 1, 2019, with the adoption of ASU 2016-02, the Company recognized operating lease right-of-use asset of \$0.8 million and operating lease liability of \$0.7 million for these leases.

The components of lease expense and related cash flows for the year ended December 31, 2019 were as follows:

	Year Ended December 31, 2019
Operating lease cost	\$ 203
Short-term lease cost	117
	320
Operating cash flows used for operating leases	\$ 198

The total rent expense was \$0.5 million for the years ended December 31, 2018 and 2017.

As of December 31, 2019, the weighted average remaining lease term and discount rate for the operating lease are 3.2 years and 6.5%, respectively.

As of December 31, 2019, maturities of lease liability due under the lease agreement are as follows:

Years Ending December 31:	Operating Leases
	(in thousands)
2020	217
2021	221
2022	177
Total lease payments	615
Less imputed interest	(54)
Total	\$ 561

In addition to base rent, these leases require payment of non-lease and non-component costs. These costs are not included in the table above.

# 7. Term Loan

In August 2018, the Company entered into a Loan and Security Agreement (Loan Agreement) with Silicon Valley Bank (SVB), pursuant to which the Company could obtain a loan of aggregate principal amount of up to \$15.0 million (Term Loans), which would become available in three tranches, each of an aggregate principal amount of up to \$5.0 million. Contemporaneously with executing the Loan Agreement, the Company drew down the first \$5.0 million tranche. In connection with the Loan Agreement, the Company

#### SIERRA ONCOLOGY, INC.

#### **Notes to Consolidated Financial Statements**

issued a warrant to SVB to purchase 1,839 of the Company's common stock at a price per share of \$74.80. The warrant was immediately exercisable, will expire on August 21, 2028, contains a cashless exercise provision and is classified as equity. With the expiration of the second and third tranches of the Term Loans during 2019, no additional warrants will be issued by the Company under the Loan Agreement.

On December 18, 2019, the Company repaid the \$5.0 million term loan and paid the prepayment and final payment fees of \$0.1 million and \$0.3 million, respectively.

The Company recognized interest expense related to the Loan Agreement of \$0.9 million for the year ended December 31, 2019, including the final payment fee, the prepayment fee and the unamortized portion of the debt issuance costs. Interest expense for the year ended December 31, 2018 was \$0.2 million.

#### 8. Commitments and Contingencies

## **Asset Purchase Agreement**

In August 2018, the Company entered into an Asset Purchase Agreement with Gilead whereby the Company acquired worldwide rights to the pharmaceutical product momelotinib, an investigational orally-bioavailable JAK1, JAK2 and ACVT1 inhibitor together with all related intellectual property rights and certain other related assets. Pursuant to the agreement, the Company made a one-time upfront payment of \$3.0 million in August 2018. The related expense was included in research and development for the year ended December 31, 2018 in the accompanying consolidated statement of operations. In October 2019, the Company entered into an amendment to the Asset Purchase Agreement in which the Company agreed to issue, subject to certain conditions, shares of common stock and a warrant to purchase common stock to Gilead in consideration for meaningfully reduced royalty rates and elimination of a near term milestone payment in the Asset Purchase Agreement. Pursuant to the amended agreement, milestone payments of up to an aggregate of \$190.0 million may become payable to Gilead upon the achievement of certain regulatory and commercial milestone events and the Company is now required to pay Gilead low double-digit to high-teens percent tiered combined royalties based upon net sales. The effectiveness of the amendment and the issuance of the shares of common stock and warrant to Gilead was conditional upon the completion of an offering that closed in November 2019.

In connection with obligations under the amendment, the Company initially recognized a \$6.5 million non-cash expense based on the fair value of the securities to be issued, which was included in research and development expense. Upon remeasurement of the securities issuance obligation at December 31, 2019, an additional \$4.0 million of non-cash expense was recorded in research and development expense. See *Note 4*, *Fair Value Measurement* for further discussions in valuation techniques.

On January 31, 2020, the Company fulfilled the obligation to issue securities by entering into a securities purchase agreement with Gilead, pursuant to which the Company issued to Gilead 725,283 shares of the Company's common stock and a warrant to purchase 725,283 common stock at a price per share of \$13.20. The warrant is immediately exercisable, will expire on January 31, 2025 and contains a cash and/or cashless exercise provision.

#### **License Agreements**

In September 2016, the Company entered into an exclusive license agreement with CRT Pioneer Fund LP (CPF) for worldwide rights, know-how and materials to develop SRA737, a small molecule inhibitor targeting Chk1, a promising therapeutic target to treat cancer. Pursuant to the agreement, the Company made a one-time upfront payment of \$7.0 million to CPF in October 2016 and paid \$2.0 million to CPF in January 2017 for the successful transfer of two ongoing Phase 1 clinical trials. Additional milestone

#### SIERRA ONCOLOGY, INC.

#### **Notes to Consolidated Financial Statements**

payments of up to an aggregate of \$319.5 million may become payable to CPF upon the achievement of certain developmental, regulatory and commercial milestones, including a milestone payment of \$7.5 million upon the dosing of the first patient in the first Phase 1 trial of SRA737 in the United States, and a payment of \$12.0 million upon the dosing of the first patient of a randomized Phase 2 trial of SRA737. In the event that the milestone payment for Phase 2 becomes due, but no milestone payment for Phase 1 has been paid, then the milestone payment for Phase 1 will become due and payable contemporaneously with the payment for the Phase 2 milestone for an aggregate payment of \$19.5 million. These milestones will be accrued once they are considered probable of occurring. In addition, the Company is required to pay CPF, on a product-by-product and country-by-country basis, tiered high single-digit to low double-digit royalties on the net sales of any product successfully developed.

In May 2016, the Company entered into an exclusive license agreement (Carna License Agreement) with Carna Biosciences, Inc. (Carna) for worldwide rights to develop and commercialize SRA141, a small molecule kinase inhibitor targeting Cdc7. In exchange for this exclusive right, the Company paid Carna an upfront payment of \$0.9 million in June 2016. The Company will be required to pay Carna milestone payments of up to an aggregate of \$270.0 million upon achievement of certain developmental, regulatory and commercial milestone events, including a milestone payment of \$4.0 million upon dosing of the first patient in the first Phase 1 clinical trial for SRA141. These milestones will be accrued once they are considered probable of occurring. As of December 31, 2019, the Company had not recorded any milestone payments to Carna. In addition, the Company is required to pay Carna tiered single-digit royalties on net sales of product candidates (as defined under the Carna License Agreement).

## Legal

From time to time, the Company may become subject to other legal proceedings, claims and litigation arising in the ordinary course of business. In addition, the Company may receive letters alleging infringement of patent or other intellectual property rights. The Company is not currently a party to any other material legal proceedings, nor is it aware of any pending or threatened litigation that, in the Company's opinion, would have a material adverse effect on the business, operating results, cash flows or financial condition should such litigation be resolved unfavorably.

## 9. Common Stock Reserved for Issuance

The Company is required to reserve and keep available out of its authorized but unissued shares of common stock a number of shares sufficient to effect the conversion of all outstanding preferred stock, options granted and available for grant under the incentive plans, shares reserved for issuance under the employee stock purchase plan and issued warrant.

	Decembei	r <b>31</b> ,
	2019	2018
Shares reserved for conversion of Series A Preferred Stock	7,803,273	_
Shares reserved under Series A warrant	7,802,241	
Shares reserved under Series B warrant	2,574,727	_
Outstanding stock options under equity incentive plans	326,023	262,539
Shares reserved for future option grants under equity plans	51,514	48,689
Shares reserved under the 2015 employee stock purchase plan	17,500	17,500
Shares reserved under warrant upon contingent events	_	3,677
Outstanding warrant	1,839	1,839
Total common stock reserved for issuance	18,577,117	334,244

#### SIERRA ONCOLOGY, INC.

#### **Notes to Consolidated Financial Statements**

On January 21, 2020 the Company's stockholders approved an increase to the authorized number of shares available for issuance under the 2015 Equity Incentive Plan by 4,312,500 (see Note 12).

On January 31, 2020 the Company fulfilled its securities issuance obligation and issued Gilead 725,283 shares of the Company's common stock and a warrant to purchase 725,283 common stock (see Note 8).

#### 10. Preferred Stock

As of December 31, 2019, the Company had 10,000,000 shares of preferred stock authorized with a par value of \$0.001. There were 103,000 shares of Series A Preferred Stock outstanding as of December 31, 2019. There were no shares of preferred stock issued and outstanding as of December 31, 2018.

## **Series A Convertible Voting Preferred Stock**

On November 13, 2019, the Company issued 103,000 shares of Series A Preferred Stock together with Series A warrants and Series B warrants for a combined purchase price of \$1,000. The aggregate proceeds received by the Company was \$97.7 million, net of underwriting discounts and commissions and offering expenses.

Each share of Series A Preferred Stock is convertible into shares of the Company's common stock equal to the stated value of the Series A Preferred Stock of \$1,000 divided by the voting conversion price of \$13.20. Each share of Series A Preferred Stock will convert into shares of common stock (i) at the option of the holder or (ii) automatically upon the fifth day of trading following the announcement of the stockholder approval for a Reverse Stock Split, subject to certain beneficial ownership limitations.

The Series A Preferred Stock will initially vote together with the Company's common stock on an as-converted basis. Holders of each Series A Preferred Stock will be entitled to one vote for each share of common stock into which their Series A Preferred Stock is then-convertible. Following the date the Series A Preferred Stock automatically converts into shares of the Company's common stock, except otherwise required by law, the Series A Preferred Stock will have no voting rights.

In the event of any voluntary or involuntary liquidation, dissolution, winding up of the Company or sale event, the assets of the Company available for distribution to its stockholders shall be distributed among the holders of the shares of Series A Preferred Stock and common stock, pro rata based on the number of shares held by each such holder.

On January 29, 2020, all shares of Series A Preferred Stock converted into 7,803,273 shares of the Company's common stock.

## 11. Warrant Liabilities

In connection with the Company's November 2019 public offering of the Series A Preferred Stock, the Company issued Series A warrants to purchase up to 7,802,241 shares of common stock at an exercise price equal to \$13.20, and Series B warrants to purchase up to 2,574,727 shares of common stock at an exercise price equal to \$13.20. Both Series A and Series B warrants are exercisable following stockholder approval of an increase in authorized common stock sufficient to allow for the exercise of the warrants, subject to certain beneficial ownership limitations. The Series A warrants will expire five years from the date they first became exercisable or on January 22, 2025 and contain a cash and/or cashless exercise provision. The Series B warrants will expire on the 75th day anniversary following the announcement of top-line data from the Company's MOMENTUM Phase 3 clinical trial of momelotinib and may only be exercised by paying the exercise price in cash, which would amount to approximately \$34.0 million in proceeds to the Company if fully exercised.

#### SIERRA ONCOLOGY, INC.

#### **Notes to Consolidated Financial Statements**

The fair values of the Series A and Series B warrants were estimated to be \$25.0 million at the date of issuance and were classified as warrant liabilities. The Company revalued the warrant liabilities at December 31, 2019 using the Black-Scholes option pricing model, and the fair value of the warrants were estimated to be \$45.9 million as at December 31, 2019. The Company recorded a \$20.9 million non-cash expense relating to the change in fair value of warrant liabilities in other income (expense), net in the accompanying consolidated statement of operations for the period ended December 31, 2019 (see Note 4).

#### 12. Stock-Based Compensation

In the accompanying consolidated statement of operations, the Company recognized stock-based compensation expense for its employees and non-employees as follows:

	Year Ended December 31,		
	2019	2018	2017
		(in thousands)	
Research and development	\$3,873	\$4,499	\$3,966
General and administrative	1,822	2,297	1,939
Total stock-based compensation	\$5,695	\$6,796	\$5,905

On January 1, 2019, the Company adopted FASB ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which aligns the guidance for share-based payments issued for goods and services for employees and nonemployees. The adoption of this new accounting guidance did not have a material impact on the Company's consolidated financial statements.

#### **Determination of Fair Value**

The estimated grant-date fair value of all the Company's stock-based awards was calculated using the Black-Scholes option pricing model, based on the following assumptions:

	Year Ended December 31,		
	2019	2018	2017
Expected term (in years)	5.3 –	5.3 –	5.3 –
	6.9	7.0	7.0
Expected volatility	89 –	88 –	86 –
	94%	91%	96%
Risk-free interest rate	1.6 –	2.6 –	1.8 –
	2.6%	3.1%	2.3%
Expected dividend rate	— %	— %	— %

The fair value of each stock option grant was determined by the Company on the date of grant using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment and estimation by management.

Expected Term—The expected term represents the period that stock-based awards are expected to be outstanding. As the Company's historical share option exercise is limited due to a lack of sufficient data points, and does not provide a reasonable basis upon which to estimate an expected term, the expected term is derived by using the midpoint between the vesting commencement date and the contractual expiration period of the stock-based award.

*Expected Volatility*—Since the Company has limited information on the volatility of common stock due to its short trading history, the expected volatility is derived from the historical stock volatilities of comparable peer public companies within its industry that are considered to be comparable to the Company's business over a period equivalent to the expected term of the stock-based awards.

#### SIERRA ONCOLOGY, INC.

#### **Notes to Consolidated Financial Statements**

*Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the stock-based awards' expected term.

*Expected Dividend Rate*—The expected dividend is zero as the Company has not paid nor anticipate paying any dividends on its common stock in the foreseeable future.

Forfeiture Rate—The Company accounts for forfeitures when they occur.

## **Equity Incentive Plans**

## 2018 Equity Inducement Plan

In September 2018, the Company's Compensation Committee approved the 2018 Equity Inducement Plan (2018 Plan). The number of shares available for awards under the 2018 Plan was set to 37,500. The exercise price of each stock-based award issued under the 2018 Plan is required to be no less than the fair value of the Company's capital stock. The vesting and exercise provisions of options or restricted awards granted are determined individually with each grant. Stock options have a 10-year life and expire if not exercised within that period or if not exercised within three months of cessation of employment with the Company or such longer period of time as specified in the option agreement.

#### 2015 Plan

The 2015 Equity Incentive Plan (2015 Plan) became effective on July 14, 2015. As of December 31, 2019, 291,191 shares were reserved for issuance under the 2015 Plan. The number of shares reserved for issuance under the 2015 Plan will increase automatically on January 1 of each calendar year 2016 through 2025 by the number of shares equal to 4% of the total outstanding shares of the Company's common stock as of the immediately preceding December 31. The Company's Board of Directors or Compensation Committee may reduce the amount of the increase in any particular year. The exercise price of each stock-based award issued under the 2015 Plan is required to be no less than the fair value of the Company's capital stock. The vesting and exercise provisions of options or restricted awards granted are determined individually with each grant. Stock options have a 10-year life and expire if not exercised within that period or if not exercised within three months of cessation of employment with the Company or such longer period of time as specified in the option agreement.

On January 21, 2020 the Company's stockholders approved the following amendments to the 2015 Plan: (i) increase to the authorized number of shares available for issuance by 4,312,500 shares and proportionately increase the share limit related to incentive stock options, (ii) provide limits on the total value of compensation that may be granted to any non-employee director in each calendar year, and (iii) eliminate the annual individual grant limit to reflect changes to the tax law in 2017 tax legislation.

#### 2008 Plan

The Company granted options under the 2008 Stock Plan (2008 Plan) until July 2015 when it was terminated as to future awards, although it continues to govern the terms of options that remain outstanding under the 2008 Plan. The 2008 Plan provided for the granting of Incentive Stock Options (ISO), nonqualified stock options and stock purchase rights. In connection with the Board of Director's approval of the 2015 Plan, all remaining shares available for future award under the 2008 Plan were transferred to the 2015 Plan, and the 2008 Plan was terminated.

## SIERRA ONCOLOGY, INC.

## **Notes to Consolidated Financial Statements**

A summary of activity under the 2008 Plan, 2015 Plan and 2018 Plan and related information is as follows:

		Options Outstanding				
	Shares Available for Grant	Number of Shares Outstanding	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (Years)	Int Va Outs O <sub>l</sub>	gregate trinsic due of standing ptions ousands)
Outstanding—December 31, 2018	48,689	262,539	\$ 114.46	7.80	\$	545
Awards authorized under the 2015 Plan	74,365					
Options granted	(94,820)	94,820	66.54			
Options exercised	_	(8,056)	55.23			
Options forfeited/cancelled	23,280	(23,280)	106.43			
Outstanding—December 31, 2019	51,514	326,023	\$ 102.56	7.45	\$	11
Exercisable—December 31, 2019		199,739	\$ 119.96	6.57	\$	_
Vested and expected to vest—December 31, 2019		326,023	\$ 102.56	7.45	\$	11

The weighted-average grant date fair values of options granted during the years ended December 31, 2019, 2018 and 2017 was \$50.40, \$70.00 and \$43.60 per share. The aggregate intrinsic value of options exercised was \$0.1 million, \$0.2 million and \$0.2 million for the years ended December 31, 2019, 2018 and 2017. The total grant date fair value of options vested for the years ended December 31, 2019, 2018 and 2017 was \$6.0 million, \$5.9 million and \$6.5 million.

As of December 31, 2019, total unrecognized stock-based compensation related to unvested stock options was \$6.0 million, which the Company expects to recognize over a remaining weighted-average period of 2.5 years.

## 2015 Employee Stock Purchase Plan

The Company adopted the 2015 Employee Stock Purchase Plan (ESPP) and initially reserved 17,500 shares of common stock as of its effective date of July 15, 2015. The aggregate number of shares issued over the term of the 2015 Employee Stock Purchase Plan will not exceed 85,000 shares of common stock. The ESPP will not become effective until such time as the Compensation Committee determines in the future, and as of December 31, 2019, the initial offering periods had not commenced. As of December 31, 2019, no shares of common stock have been issued to employees participating in the ESPP and 17,500 shares were available for issuance under the ESPP.

## 13. Income Taxes

The geographical breakdown of loss before provision for income taxes is as follows:

Year	r 31,	
2019	2018	2017
	(in thousands)	
\$(89,459)	\$(54,395)	\$(42,425)
1,024	758	566
\$(88,435)	\$(53,637)	\$(41,859)
	\$(89,459) 1,024	(in thousands) \$(89,459) \$(54,395) 1,024 758

## SIERRA ONCOLOGY, INC.

## **Notes to Consolidated Financial Statements**

The components of the provision for (benefit from) income taxes are as follows:

	Year	r Ended December	31,
	2019	2018	2017
		(in thousands)	
Current tax provision (benefit):			
Federal	\$ —	\$ —	\$ —
State	_	_	_
Foreign	85	(180)	183
Total current tax provision (benefit)	85	(180)	183
Deferred tax provision (benefit):			
Foreign	(245)	(122)	(27)
Total deferred tax provision (benefit)	\$(245)	\$(122)	\$ (27)
Total provision for (benefit from) income taxes	\$(160)	\$(302)	\$ 156

The reconciliation between income taxes computed at the federal statutory income tax rate and the provision for (benefit from) income taxes is as follows:

	Year Ended December 31,		
	2019	2018	2017
Federal statutory rate	21.0%	21.0%	34.0%
Effect of:			
Effect of ownership change on deferred tax assets	(29.0)	_	(84.8)
Change in valuation allowance	12.4	(22.2)	69.5
Warrant issuance and remeasurement	(5.3)	_	_
Federal tax credit	1.5	2.4	(0.9)
State income tax benefit, net of federal benefit	0.2	0.3	0.1
US tax reform deferred impact on tax rate change	_	_	(17.3)
Other permanent items	(0.6)	(1.0)	(1.0)
Total provision for (benefit from) income taxes	0.2%	0.5%	(0.4)%

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (Tax Act). The Tax Act significantly revised U.S. tax law by, among other provisions, lowering the U.S. federal statutory income tax rate from 35% to 21%. To account for the rate reduction, the Company recorded a decrease of its net deferred tax assets of \$7.2 million for the period ended December 31, 2017. This did not have an impact on the Company's financial statements since its U.S. deferred tax assets are fully offset by a valuation allowance.

#### SIERRA ONCOLOGY, INC.

#### **Notes to Consolidated Financial Statements**

The components of the deferred tax assets are as follows:

	Decemb	er 31,
	2019	2018
	(in thou	sands)
Deferred tax assets:		
59 (e) expenditures and amortization	\$ 5,902	\$ 1,435
Stock based compensation	4,663	3,642
Net operating loss carryforwards	2,649	18,347
License fee	2,538	2,008
Research and development credits	486	1,137
Other	967	972
Gross deferred tax assets	17,205	27,541
Valuation allowance	(16,441)	(27,317)
Total deferred tax assets	764	224
Deferred tax liabilities:		
Lease Asset	244	_
Other	90	39
Total deferred tax liabilities	334	39
Total net deferred tax assets	\$ 430	\$ 185

Recognition of deferred tax assets is appropriate when realization of these assets is more likely than not. Based upon the weight of available evidence, which includes historical operating performance and the recorded cumulative net losses in prior fiscal periods, the Company recorded a full valuation allowance of \$16.4 million and \$27.3 million against the net U.S. deferred tax assets as of December 31, 2019 and 2018. The net valuation allowance decreased by \$10.9 million for the year ended December 31, 2019. The net valuation allowance increased by \$11.9 million for the year ended December 31, 2018.

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing U.S. deferred tax assets. Based on the weight of all evidence, including a history of operating losses and the Company's ability to generate future taxable income to realize the assets, management has determined that it is more likely than not that the U.S. deferred tax assets will not be realized.

Utilization of the Company's net operating loss and U.S. research and development credit carryforwards to offset taxable income are subject to an annual limitation, pursuant to Internal Revenue Code (IRC) Sections 382 and 383. As a result of the stock offering that occurred in November 2019 an ownership change under Section 382 is deemed to have occurred. As such, certain of the Company's tax attributes existing as of the date of the ownership change are not be available for future use. The loss of these attributes does not have any impact on the financial statements since the net U.S. deferred tax assets are offset by a full valuation allowance.

As of December 31, 2019, the Company has gross U.S. federal tax net operating loss carryforwards of \$1.2 million, that are eligible for indefinite carryforward, and gross state operating loss carryforwards of \$50.7 million expiring in years ranging from 2022 to 2039. The Company also has U.S. net tax credit carryforwards of \$0.1 million which expire in 2039 and net tax credit carryforwards in a foreign jurisdiction of \$0.4 million which begin to expire in 2038.

#### SIERRA ONCOLOGY, INC.

#### **Notes to Consolidated Financial Statements**

#### **Uncertain Tax Positions**

The activity related to the gross amount of unrecognized tax benefits is as follows:

	Year Ended December 3		
	2019	2018	2017
		(in thousands)	
Beginning balance	\$ 264	\$ 43	\$ 311
Increases based on tax positions related to prior years	_	109	_
Decreases based on tax positions related to prior years	(103)	_	(79)
Decreases due to ownership change	_	_	(232)
Increases based on tax positions in current year	153	112	43
Settlement	_	_	_
Lapse of statute of limitations	_	_	_
Ending balance	\$ 314	\$264	\$ 43

If recognized, gross unrecognized tax benefits would not have a material impact on the Company's effective tax rate due to the Company's full valuation allowance position on the U.S. deferred tax assets. From time to time, the Company is subject to review by tax authorities. It is not possible to estimate the impact of changes, if any, to previously recorded uncertain tax positions. However, the Company does not expect the changes, if any, to be materially different from what is recorded and will adjust its estimate and liability as necessary.

The Company recognizes interest and penalties related to unrecognized tax benefits in the provision for income taxes in the accompanying consolidated statement of operations. Accrued interest and penalties, if applicable, are included in accrued liabilities in the consolidated balance sheet. For the years ended December 31, 2019 and 2018, the Company did not recognize any accrued interest and penalties.

The Company is subject to taxation in the United States, various states, Canada and Australia. Tax years 2016 through 2018 remain open to examination by the United States, various state jurisdictions and Canada. The tax year ended December 31, 2018 remains open to examination in Australia. Other than routine reviews by tax authorities for tax credits claimed, the Company is not under examination in any tax jurisdiction for any year.

## 14. Selected Quarterly Financial Data (Unaudited)

The following tables present certain selected unaudited consolidated quarterly financial information for each of the eight quarters ended December 31, 2019. This consolidated quarterly information has been prepared on the same basis as the consolidated financial statements and includes all adjustments necessary to state fairly the information for the periods presented. The selected consolidated quarterly financial results from operations for the years ended December 31, 2019 and 2018 are set forth therein. Net loss per share for all periods presented has been retroactively adjusted to reflect the 1-for-40 reverse stock split effected on January 22, 2020 as described in Note 1.

	Fiscal 2019 Quarter Ended						
	March 31, 2019	· · · · · · · · · · · · · · · · · ·				December 31, 2019 (2)	
	(in thousands, except per share amounts)						
Operating expenses	\$ 13,502	\$ 15,207	\$	13,264	\$	25,019	
Net loss(1)	\$(13,032)	\$(14,878)	\$	(12,903)	\$	(47,462)	
Basic and diluted net loss per share	\$ (7.00)	\$ (7.97)	\$	(6.91)	\$	(7.88)	

# SIERRA ONCOLOGY, INC.

# **Notes to Consolidated Financial Statements**

		Fiscal 2018 Quarter Ended						
	March 31, 2018	· · · · · · · · · · · · · · · · ·			December 31, 2018			
		(in thousands, except per share amounts)				_		
Operating expenses	\$ 11,754	\$ 12,963	\$	16,051	\$	14,649		
Net loss(1)	\$(11,525)	\$(11,960)	\$	(15,567)	\$	(14,283)		
Basic and diluted net loss per share	\$ (7.72)	\$ (6.44)	\$	(8.38)	\$	(7.68)		

- (1) Net loss from continuing operations and net loss attributable to holders of common stock and preferred stock with characteristics of common stock are the same as net loss for all periods presented.
- (2) Net loss for the quarter ended December 31, 2019 included a \$20.9 million non-cash charge relating to changes in fair value of warrant liabilities (see Note 11) and a \$10.5 million non-cash charge relating to the Company's obligation to issue securities pursuant to an amendment to the Asset Purchase Agreement with Gilead (see Note 8).

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

None.

#### Item 9A. Controls and Procedures.

#### **Evaluation of Disclosure Controls and Procedures**

As of December 31, 2019, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2019, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

## Management's Annual Report on Internal Control Over Financial Reporting

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to exemptions provided to issuers that qualify as an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. However, for as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As of December 31, 2019, management assessed the effectiveness of our internal control over financial reporting based on the framework established in "Internal Control—Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013 Framework). Based on this evaluation, management has determined that our internal control over financial reporting was effective as of December 31, 2019.

#### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

#### PART III

## Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

#### Item 11. Executive Compensation.

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

## Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

## **PART IV**

# Item 15. Exhibits, Consolidated Financial Statement Schedules.

(a) The following documents are filed as part of this report:

## 1. Consolidated Financial Statements

See Index to Consolidated Financial Statements at Item 8 herein.

# 2. Consolidated Financial Statement Schedules

No consolidated financial statement schedules are provided because the information called for is not required or is shown either in the consolidated financial statements or notes thereto.

## 3. Exhibits

T 1914		Incorporated by reference					
Exhibit <u>Number</u>	Description of Document	Form	File No.	<u>Exhibit</u>	Filing Date	Filed <u>Herewith</u>	
2.1+†	Asset Purchase Agreement dated August 20, 2018 by and between the Registrant and YM Biosciences Australia Pty Ltd. and Gilead Sciences, Inc.	10-Q	001-37490	2.1	November 8, 2018		
2.2++	Amendment to Asset Purchase Agreement dated October 28, 2019, by and between the Registrant and YM Biosciences Australia Pty Ltd. and Gilead Sciences, Inc.					X	
3.1	Restated Certificate of Incorporation.	S-1	333-204921	3.2	June 12, 2015		
3.2	Certificate of Amendment to the Restated Certificate of Incorporation.	8-K	001-37490	3.1	January 22, 2020		
3.3	Restated Bylaws.	S-1	333-204921	3.4	June 12, 2015		
3.4	<u>Certificate of Designation of Preferences, Rights and Limitations, with respect to the Series A Convertible Voting Preferred Stock.</u>	8-K	001-37490	3.1	November 13, 2019		
4.1	Form of Common Stock Certificate.	S-1	333-204921	4.1	July 6, 2015		
4.2	Third Amended and Restated Investor Rights Agreement, dated April 17, 2014, by and among the Registrant and certain of its stockholders, as amended.	S-1	333-204921	4.2	June 12, 2015		
4.3	Warrant dated August 21, 2018 issued to Silicon Valley Bank	10-Q	001-37490	4.1	November 8, 2018		
4.4	Form of Series A Preferred Stock Certificate	8-K	001-37490	4.1	November 13, 2019		
4.5	Description of Securities					X	

		Incorporated by reference				
Exhibit <u>Number</u>	Description of Document	Form	File No.	Exhibit	Filing Date	Fi <u>Here</u>
4.6	Form of Series A Convertible Voting Preferred Stock Certificate	8-K	001-37490	3.1	November 13, 2019	
4.7	Form of Series A Warrant	8-K	001-37490	4.1	November 7, 2019	
4.8	Form of Series B Warrant	8-K	001-37490	4.2	November 7, 2019	
4.9	Securities Purchase Agreement by and between the Company and Gilead Sciences, Inc.	8-K	001-37490	10.1	February 6, 2020	
4.10	Form of Warrant to Gilead Sciences, Inc.	8-K	001-37490	10.2	February 6, 2020	
10.1*	Form of Indemnification Agreement.	S-1	333-204921	10.1	June 12, 2015	
10.2*	2008 Stock Plan, as amended, and forms of award agreements thereunder.	S-1	333-204921	10.2	June 12, 2015	
10.3*	2015 Equity Incentive Plan, as amended, and forms of award agreements thereunder.					>
10.4*	2015 Employee Stock Purchase Plan.	S-1	333-204921	10.4	July 6, 2015	
10.5*	2018 Equity Inducement Plan and forms of award agreements thereunder.	10-Q	001-37490	10.2	November 8, 2018	
10.6*	Form of Executive Officer Employment Agreement.	S-1	333-204921	10.5	July 6, 2015	
10.7	Form of Amendment to Executive Officer Employment Agreement (other than Chief Executive Officer)	10-Q	001-37490	10.1	May 9, 2017	
10.8*	Form of Employment Agreement between the Registrant and Nick Glover.	S-1	333-204921	10.7	July 6, 2015	
10.9+	<u>License Agreement dated May 26, 2016 between the Registrant and Carna Biosciences, Inc.</u>	10-Q	001-37490	10.1	August 12, 2016	
10.10+	<u>License Agreement dated September 27, 2016 by and between</u> the Registrant and CRT Pioneer fund LP.	10-Q	001-37490	10.1	November 10, 2016	
10.11	Office Lease, dated June 12, 2017, by and between Sierra Oncology Canada ULC and The Cadillac Fairview Corporation Limited, as the duly authorized agent of Ontrea Inc. and Van885 West Georgia GP Ltd., the general partner of Van885 West Georgia LP.	10-Q	001-37490	10.1	August 10, 2017	

			Incorporated by reference				
Exhibit <u>Number</u>	Description of Document	Form	File <u>No.</u>	<b>Exhibit</b>	Filing Date	Filed <u>Herewith</u>	
21.1	Subsidiaries of the Registrant.					X	
23.1	Consent of independent registered public accounting firm.					X	
24.1	Power of Attorney. Reference is made to the signature page hereto.					X	
31.1	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X	
31.2	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X	
32.1**	Certification of Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X	
32.2**	Certification of Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X	
101.INS	XBRL Instance Document.					X	
101.SCH	XBRL Schema Linkbase Document.					X	
101.CAL	XBRL Calculation Linkbase Document.					X	
101.DEF	XBRL Definition Linkbase Document.					X	
101.EXT	XBRL Extension label Linkbase Document.					X	
101.PRE	XBRL Presentation Linkbase Document.					X	

\* Executive compensation plan or agreement.

++ Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.

<sup>\*\*</sup> This certification is deemed not filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

<sup>+</sup> Confidential treatment has been granted for portions of this exhibit under Rule 24b-2 promulgated under the Exchange Act. The Registrant has omitted and filed separately with the SEC the confidential portions of this exhibit.

† Schedules and similar attachments to the agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish supplementally a copy of any omitted schedule or similar attachment to the SEC upon request.

# Item 16. Form 10-K Summary.

None.

## **SIGNATURES**

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

Date: March 3, 2020

### SIERRA ONCOLOGY, INC.

By: /s/ Nick Glover
Nick Glover
President and Chief Executive Officer

#### POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Nick Glover and Sukhi Jagpal, 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 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.

<u>Signature</u>	<u>Title</u>	Date
/s/ Nick Glover Nick Glover	President, Chief Executive Officer and Director (Principal Executive Officer)	March 3, 2020
/s/ Sukhi Jagpal Sukhi Jagpal	Chief Financial Officer (Principal Accounting and Financial Officer)	March 3, 2020
/s/ Robert Pelzer Robert Pelzer	Chairman of the Board	March 3, 2020
/s/ Gaurav Aggarwal Gaurav Aggarwal	Director	March 3, 2020
/s/ Andrew Allen Andrew Allen	Director	March 3, 2020
/s/ Mona Ashiya Mona Ashiya	Director	March 3, 2020
/s/ Jeffrey H. Cooper Jeffrey H. Cooper	Director	March 3, 2020
/s/ Josh Richardson  Josh Richardson	Director	March 3, 2020
/s/ Andrew Sinclair Andrew Sinclair	Director	March 3, 2020

CERTAIN IDENTIFIED INFORMATION HAS BEEN OMITTED FROM THIS DOCUMENT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED, AND HAS BEEN MARKED WITH "[\*\*\*]" TO INDICATE WHERE OMISSIONS HAVE BEEN MADE.

#### **AMENDMENT**

#### TO ASSET PURCHASE AGREEMENT

This Amendment to the Asset Purchase Agreement (this "Amendment") effective as of October 28, 2019 (the "Amendment Date"), is made by and among Sierra Oncology, Inc., a Delaware corporation ("Buyer"), YM Biosciences Australia Pty Ltd, a company organized under the laws of Australia ("Seller"), and Gilead Sciences, Inc., a Delaware corporation ("GSI"). Seller, GSI and Buyer may hereinafter be referred to individually as a "Party" and, collectively, as the "Parties".

WHEREAS, the Parties previously entered into that certain Asset Purchase Agreement dated as of August 20, 2018 (the "Agreement");

WHEREAS, the Parties wish to amend the Agreement in certain respects on the terms and conditions set forth herein.

NOW THEREFORE, capitalized terms not defined in this Amendment shall have the meaning ascribed in the Agreement, and the Parties hereby agree as follows:

- 1. <u>Amendments</u>. Effective as of, and conditioned upon the occurrence of, the Issuance Date (as defined below), the Agreement shall be amended as follows (it being understood that if the Issuance Date does not occur the following provisions shall have no effect):
- a. Section 2.9 of the Agreement shall be amended by deleting the Initiation Milestone table, including deletion of the Milestone Event and Milestone Payment for the Initiation Milestone.
  - b. Section 2.10(a) of the Agreement shall be amended by replacing the royalty table with the following:

Aggregate Net Sales	Royalty Rate
That portion of aggregate Net Sales that are less than [***] U.S. Dollars	
(\$[***]) in a calendar year	[***]%
That portion of aggregate Net Sales that are equal to or greater than [***] U.S.	
Dollars ( $\{***\}$ ) but less than $[***]$ U.S. Dollars ( $\{***\}$ ) in a calendar year	[***]%
That portion of aggregate Net Sales that are equal to or greater than [***] U.S.	
Dollars (\$[***]) but less than [***] U.S. Dollars (\$[***]) in a calendar year	[***]%
That portion of aggregate Net Sales that are equal to or greater than [***] U.S.	
Dollars (\$[***]) in a calendar year	[***]%

2. Securities Issuance. In consideration of the Parties' agreement to amend the Agreement as set forth herein, on (a) if the Financing (as defined below) is closed prior to the Outside Date (as defined below), the later of the (i) the date immediately after the date the Buyer closes a financing in which the Buyer receives gross proceeds of at least \$[\*\*\*] million (the "Financing"), and (ii) if convertible preferred stock is issued in the Financing, the date immediately after the date convertible preferred stock issued in the Financing automatically converts to common stock and (b) if no Financing is closed prior to the Outside Date, the Specified Date (as defined below) (the applicable date under clause (a) or (b) (if any), the "Issuance Date"), the Buyer and GSI shall enter into the Securities Purchase Agreement attached hereto as Exhibit A (the "SPA"), pursuant to which the Buyer shall issue to GSI shares of Buyer common stock, par value \$0.001 per share (the "Common Stock"), and a warrant to purchase Common Stock, in the form attached as Exhibit A to the SPA, with such changes thereto to provide GSI the benefit of any terms of any warrants issued in the Financing that are more favorable to the holder of such warrants than the terms of Exhibit A (the "Warrant"). The number of shares of Buyer Common Stock to be issued to GSI shall be equal to 7.5% of the Buyer's outstanding shares of Common Stock on the Issuance Date (after giving effect to the Financing, including the conversion of any convertible preferred stock issued in the Financing, the conversion, exchange or exercise into Common Stock of any other securities issued in the Financing (other than the warrants to be issued in the Financing) and the issuance of any shares of Common Stock in the Financing) (such outstanding shares, after giving effect to the foregoing, the "Financing Adjusted Shares"). The Warrant shall be exercisable to purchase up to that number of shares of Common Stock equal to 7.5% of the Buyer's Financing Adjusted Shares of Common Stock on the Issuance Date (the "Warrant Shares"), at an exercise price equal to the conversion price of the convertible preferred stock issued in the Financing, or if no such shares of convertible preferred stock are issued in a Financing, then the lower of (i) the closing stock price of the Common Stock as reported by the Nasdaq Stock Market on the date immediately prior to the Issuance Date and (ii) the exercise price of any warrants or other convertible, exercisable or exchangeable securities issued in the Financing. In the event no Financing is closed prior to [\*\*\*] (or such later date as may be specified by GSI) (the "Outside Date") then on such date mutually agreed upon by Buyer and GSI (the "Specified Date"), the Buyer and GSI shall enter into the SPA, pursuant to which the Buyer shall issue to GSI that

number of shares of Buyer Common Stock equal to 7.5% of the Buyer's outstanding shares of Common Stock as of the Specified Date and a Warrant to purchase up to 7.5% of the outstanding shares of Common Stock as of the Specified Date, at an exercise price equal to the lesser of (i) the closing stock price of the Common Stock as reported by the Nasdaq Stock Market on the Specified Date and (ii) the average closing price of the Common Stock as reported by the Nasdaq Stock Market for the five trading days immediately preceding the Specified Date. Notwithstanding the foregoing, in no event shall the Company issue Common Stock and Warrant Shares to GSI that, in the aggregate, represent 20% or more of the Company's outstanding shares of Common Stock immediately prior to the date of entry into the SPA.

3. <u>Miscellaneous</u>. This Amendment shall be effective for all purposes as of the Amendment Date, except as set forth in <u>Section 1</u>. Except as expressly modified herein, the Agreement shall continue to remain in full force and effect in accordance with its terms. This Amendment may be executed in counterparts, each of which shall be deemed to be an original and together shall be deemed to be one and the same document.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be signed by their respective representatives thereunto duly authorized, all as of the date first written above.

## YM BIOSCIENCES AUSTRALIA PTY LTD

By: /s/ Brett Pletcher

Name: Brett Pletcher Title: Director

# SIERRA ONCOLOGY, INC.

By: /s/ Nick Glover

Name: Dr. Nick Glover Title: President & CEO

# GILEAD SCIENCES, INC.

By: /s/ Jeremy Bender

Name: Jeremy Bender

Title: VP, Corporate Development

# Exhibit A

**Securities Purchase Agreement** 

#### SECURITY PURCHASE AGREEMENT

shall be revised, as applicable, to provide GSI the benefit of any terms of any warrants issued in the Financing that are more favorable to the holder of such warrants than the terms of the originally agreed Exhibit A) (the "Warrant"), registered in the name of the Purchaser, to purchase up to [] shares of the Common Stock, with an exercise price per share equal to \$[], subject to adjustment therein (the "Warrant Shares" and together with the Shares and the Warrant, the "Securities"), in consideration of the Company's and the Purchaser's agreement to amend that certain Asset Purchase Agreement dated as of August 20, 2018, as set forth in that certain Amendment to Asset Purchase Agreement dated as of October, 2019. In no event	This Security Purchase Agreement (this " <u>Agreement</u> ") is made as of
	Company's common stock, \$0.001 par value per share (the "Common Stock") and (ii) a warrant in the form attached hereto as Exhibit A (which Exhibit shall be revised, as applicable, to provide GSI the benefit of any terms of any warrants issued in the Financing that are more favorable to the holder of such warrants than the terms of the originally agreed Exhibit A) (the "Warrant"), registered in the name of the Purchaser, to purchase up to [] shares of the Common Stock, with an exercise price per share equal to \$[], subject to adjustment therein (the "Warrant Shares" and together with the Shares and the Warrant, the "Securities"), in consideration of the Company's and the Purchaser's agreement to amend that certain Asset Purchase Agreement dated as of August 20, 2018, as set forth in that certain Amendment to Asset Purchase Agreement dated as of October, 2019. In no event shall the Company issue Common Stock and Warrant Shares to GSI that, in the aggregate, represent 20% or more of the Company's outstanding shares

## 2. Closing and Delivery.

- (a) The closing ("<u>Closing</u>") of the transactions contemplated hereby shall be held at the offices of Fenwick & West LLP, 1191 Second Avenue, Floor 10, Seattle, Washington 98101 within two Business Days of the date of this Agreement (such date, the "<u>Closing Date</u>"), or at such other time and place as the Company and the Purchaser mutually agree upon. "Business Day" shall mean any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States, any day on which banking institutions in The City of New York or the State of New York are authorized or required by law or other governmental action to close and December 26, 2019 through and including January 1, 2020.
- (b) At the Closing, the Company shall execute and deliver to the Purchaser the Warrant and direct its transfer agent to issue and register the Shares in uncertificated form in the Purchaser's name (or in such nominees' or nominees' name(s) as designated by the Purchaser in writing) on the books of the Company, with the legend set forth in Section 5 of this Agreement.
  - 3. **Company Representations**. The Company represents and warrants to the Purchaser as follows:
- (a) The Company is duly incorporated, validly existing, and in good standing under the laws of the State of Delaware. The Company has all requisite power and authority to own and operate its properties and assets and to carry on its business as presently conducted and as proposed to be conducted. The Company is qualified to do business as a foreign entity in every jurisdiction in which the failure to be so qualified would have, or would reasonably be expected to have, a material adverse effect, individually or in the aggregate, upon the business, properties, tangible and intangible assets, liabilities, operations, financial condition or results of operation of the Company or the ability of the Company to perform its obligations under the Transaction Agreements (a "Material Adverse Effect").
- (b) The Company has all requisite power to execute and deliver this Agreement, to issue the Securities, and to carry out and perform its obligations under the terms of this Agreement and the Warrant (the "Transaction Agreements").
- (c) The execution, delivery, and performance of the Transaction Agreements by the Company, including the issuance, sale and delivery of the Securities, has been duly authorized by all requisite action on the part of the Company and its officers, directors and stockholders, and this Agreement constitutes the legal, valid, and binding obligation of the Company enforceable in accordance with its terms, except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, and other laws of general application affecting enforcement of creditors' rights generally, and (b) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies the "Enforceability Exceptions").

- (d) Except for any Current Report on Form 8-K and submission of a Listing of Additional Shares notice to The Nasdaq Stock Market in connection with the transaction contemplated hereby and the filing of a registration statement (if requested by the Purchaser) pursuant to the registration rights granted in Section 6 of this Agreement, the Company is not required to give any notice to, make any filing with, or obtain any authorization, consent, or approval of any government or governmental agency in order to consummate the transaction contemplated by the Transaction Agreements. Assuming the accuracy of the representations of the Purchaser in Section 4, no consent, approval, authorization or other order of, or registration, qualification or filing with, any court, regulatory body, administrative agency, self-regulatory organization or other governmental body is required for the execution, delivery or performance of the Transaction Agreements including the valid issuance, sale and delivery of the Securities, other than such as have been or will be made or obtained, or for any securities filings required to be made under federal or state securities laws applicable to the offering of the Securities.
- (e) The execution and delivery of the Transaction Agreements, the issuance, sale and delivery of the Securities by the Company, the performance by the Company of its obligations under the Transaction Agreements and/or the consummation of the transactions contemplated hereby will not (a) conflict with, result in the breach or violation of, or constitute (with or without the giving of notice or the passage of time or both) a violation of, or default under, (i) any bond, debenture, note or other evidence of indebtedness, or under any lease, license, franchise, permit, indenture, mortgage, deed of trust, loan agreement, joint venture or other agreement or instrument to which the Company or any subsidiary is a party or by which it or its properties may be bound or affected, (ii) the Company's Restated Certificate of Incorporation, as amended and as in effect on the date hereof, the Company's Bylaws, as amended and as in effect on the date hereof, or the equivalent document with respect to any subsidiary, as amended and as in effect on the date hereof, or (iii) any statute or law, judgment, decree, rule, regulation, ordinance or order of any court or governmental or regulatory body (including The Nasdaq Stock Market), governmental agency, arbitration panel or authority applicable to the Company, any of its subsidiaries or their respective properties, except in the case of clauses (i) and (iii) for such conflicts, breaches, violations or defaults that would not be likely to have, individually or in the aggregate, a Material Adverse Effect.
- (f) The Shares are duly authorized and when issued pursuant to the terms of this Agreement will be validly issued, fully paid, and non-assessable, and will be free of any liens or encumbrances with respect to the issuance thereof; provided, however, that the Shares shall be subject to restrictions on transfer under state or federal securities laws as set forth in this Agreement, or as otherwise may be required under state or federal securities laws as set forth in this Agreement at the time a transfer is proposed. The issuance and delivery of the Shares is not subject to preemptive, co-sale, right of first refusal or any other similar rights of the stockholders of the Company or any other person, or any liens or encumbrances or result in the triggering of any anti-dilution or other similar rights. Except as set forth in the Company's SEC filings and any equity awards granted pursuant to employee benefit plans described in the Company's SEC filings, there are no options, warrants, or rights to subscribe to, or securities, rights, understandings or obligations convertible into or exchangeable for, or giving any right to subscribe for, any shares of capital stock or other equity interest of the Company, and there are no outstanding agreements for preemptive or similar rights affecting the Common Stock.
- (g) The Warrants have been duly authorized by the Company and, when duly executed and delivered by the Company, will constitute a valid and binding agreement of the Company, enforceable against the Company in accordance with its terms, subject to the Enforceability Exceptions.
- (h) The Warrant Shares issuable upon exercise of the Warrants have been duly authorized and reserved for issuance upon exercise by all necessary corporate action and such shares, when issued upon such exercise in accordance of the terms of the Warrants, will be validly issued and will be fully paid and non-assessable, and will be free of any liens or encumbrances with respect to the issuance thereof; provided, however, that the Warrant Shares shall be subject to restrictions on transfer under state or federal securities laws as set forth in this Agreement, or as otherwise may be required under state or federal securities laws as set forth in this Agreement at the time a transfer is proposed. The issuance and delivery of the Warrant Shares is not subject to preemptive, co-sale, right of first refusal or any other similar rights of the stockholders of the Company or any other Person, or any liens or encumbrances or result in the triggering of any anti-dilution or other similar rights.

- (i) There is no action, claim, suit, demand, hearing, notice of violation or deficiency, or proceeding pending or, to the Company's knowledge, threatened against the Company or any of its subsidiaries by any court or governmental or regulatory body (including The Nasdaq Stock Market), governmental agency, arbitration panel or authority or any third party that would be reasonably likely, individually or in the aggregate, to enjoin, prevent or materially delay the issuance, sale and delivery of the Securities, the performance by the Company of its obligations under the Transaction Agreements or the consummation by the Company of the transactions contemplated hereby.
- (j) Neither the Company nor any of its subsidiaries, nor any person acting on its or their behalf, (i) has engaged in any form of general solicitation or general advertising (within the meaning of Regulation D under the Securities Act of 1933, as amended (the "Securities Act")) in connection with the offer or sale of the Securities, (ii) has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under any circumstances that would require registration of the Securities under the Securities Act or (iii) has issued any securities which may be integrated with the sale of the Securities to the Purchaser for purposes of the Securities Act, nor will the Company or any of its subsidiaries or affiliates take any action or steps that would require registration of any of the Securities under the Securities Act.
- (k) The Company has not engaged any brokers, finders or agents, and neither the Company nor the Purchaser has, nor will, incur, directly or indirectly, as a result of any action taken by the Company, any liability for brokerage or finders' fees or agents' commissions or any similar charges in connection with this Agreement.
- 4. <u>Purchaser Representations</u>. In connection with the receipt of the Securities pursuant to this Agreement, the Purchaser represents to the Company the following:
- (a) The execution and delivery by the Purchaser of this Agreement, and the acquisition by the Purchaser of the Securities under this Agreement, do not contravene or constitute a default under, or violation of, (i) any agreement (or require the consent of any party under any such agreement that has not been made or obtained) to which the Purchaser is a party, or (ii) any judgment, injunction, order, decree or other instrument binding upon the Purchaser, in each case except where such contravention, default, violation or failure to obtain a consent, individually or in the aggregate, would not reasonably be expected to impair Purchaser's ability to acquire the Securities under this Agreement.
- (b) The Purchaser understands the definition of the term "accredited investor" within the meaning of Regulation D, Rule 501(a), promulgated by the SEC under the Securities Act, and qualifies as an accredited investor.
- (c) The Purchaser is aware of the Company's business affairs and financial condition and has acquired sufficient information about the Company to reach an informed and knowledgeable decision to acquire the Securities. The Purchaser is acquiring the Securities for investment for its own account only and not with a view to, or for resale in connection with, any "distribution" thereof within the meaning of the Securities Act or under any applicable provision of state law. The Purchaser does not have any present intention to transfer the Securities to any other person or entity in such a "distribution."
- (d) The Purchaser understands that the Securities have not been registered under the Securities Act by reason of a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of the Purchaser's investment intent as expressed herein.
- (e) The Purchaser understands that the Securities are "restricted securities" under applicable U.S. federal and state securities laws and that, pursuant to these laws, the Purchaser must hold the Securities indefinitely unless they are registered with the SEC and, if applicable, qualified by state authorities, or sold or otherwise disposed of in a transaction exempt from, or not subject to, such registration and qualification requirements. The Purchaser acknowledges that the Company has no obligation to register or qualify the Securities for resale, except as set forth in Section 6 of this Agreement.

- (f) By reason of its business and financial experience, the Purchaser has the ability to protect its own interests in connection with the purchase of the Securities.
- (g) The Purchaser has not engaged any brokers, finders or agents, and neither the Company nor the Purchaser has, nor will, incur, directly or indirectly, as a result of any action taken by the Purchaser, any liability for brokerage or finders' fees or agents' commissions or any similar charges in connection with this Agreement.
- (h) The Purchaser has reviewed with its own tax advisors the U.S. federal, state, local and foreign tax consequences of this investment and the transactions contemplated by this Agreement. With respect to such matters, the Purchaser relies solely on such advisors and not on any statements or representations of the Company or any of its agents, written or oral. The Purchaser understands that it (and not the Company) shall be responsible for its own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

## 5. Restrictive Legends and Stop-Transfer Orders.

(a) Each certificate, instrument or book entry evidencing the Securities shall (unless otherwise permitted by applicable securities law) be notated with a legend substantially similar to the following (in addition to any legend required by state securities laws):

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR UNDER THE SECURITIES LAWS OF CERTAIN STATES. THESE SECURITIES MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED EXCEPT AS PERMITTED UNDER THE ACT AND APPLICABLE STATE SECURITIES LAWS IN ACCORDANCE WITH APPLICABLE REGISTRATION REQUIREMENTS OR AN EXEMPTION THEREFROM. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE ISSUER THAT SUCH OFFER, SALE OR TRANSFER, PLEDGE OR HYPOTHECATION OTHERWISE COMPLIES WITH THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS.

- (b) The Purchaser consents to the Company making a notation on its records and giving instructions to any transfer agent in order to implement the restrictions on transfer established in this Section 5.
- (c) The legend referring to federal and state securities laws identified in Section 5(a) notated on any certificate or book entry evidencing the Securities and the stock transfer instructions and record notations with respect to such Securities shall be removed, and the Company shall issue a certificate without such legend to the holder of such Securities (to the extent the securities are certificated), if (i) such securities are registered under the Securities Act, or (ii) such holder provides the Company with an opinion of counsel reasonably acceptable to the Company to the effect that such legend may be removed from such Securities or that a sale or transfer of such Securities may be made without registration, qualification or legend.
- 6. **Registration Rights**. Following the Closing, upon the request of the Purchaser, the Company and the Purchaser will enter into a registration rights agreement providing the Purchaser with customary demand (including for a shelf registration if available) for resale of the Shares and Warrant Shares (and any other shares of capital stock or other equity interests issued or issuable to the Purchaser thereunder).

#### 7. Miscellaneous.

- (a) This Agreement and all acts and transactions pursuant hereto and the rights and obligations of the parties hereto shall be governed, construed and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts of law.
- (b) This Agreement may be executed in two counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument.
- (c) The rights and benefits of this Agreement shall inure to the benefit of, and be enforceable by the Company's successors and assigns. The rights and obligations of the Purchaser under this Agreement may only be assigned either to an affiliate of the Purchaser or with the prior written consent of the Company. The rights and obligations of the Company under this Agreement may only be assigned with the prior written consent of the Purchaser. No person or entity not a party to this Agreement shall be deemed to be a third-party beneficiary hereunder or entitled to any rights hereunder.
  - (d) All representations, warranties, covenants and agreements contained in this Agreement shall survive indefinitely.
- (e) No modifications or amendments to, or waivers of, any provision of this Agreement may be made, except pursuant to a document signed by the Company and the Purchaser.
- (f) When a reference is made in this Agreement to Sections, paragraphs, clauses or Annexes, such reference shall be to a Section, paragraph, clause or Annex to this Agreement unless otherwise indicated. The words "include," "includes," and "including" when used herein shall be deemed in each case to be followed by the words "without limitation." The headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. This Agreement has been negotiated by the respective parties hereto and their attorneys and the language hereof will not be construed for or against any party. The words "hereof," "herein," "herewith," "hereby" and "hereunder" and words of similar import shall, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement.
- (g) This Agreement and all other documents required to be delivered pursuant hereto constitute the entire agreement among the parties with respect to the subject matter hereof and supersede all prior documents, agreements and understandings, both written and verbal, among the parties with respect to the subject matter hereof and the transactions contemplated hereby.
- (h) If any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws, then, if possible, such illegal, invalid or unenforceable provision will be modified to such extent as is necessary to comply with such present or future laws and such modification shall not affect any other provision hereof; <u>provided</u> that if such provision may not be so modified, such illegality, invalidity or unenforceability will not affect any other provision, but this Agreement will be reformed, construed and enforced as if such invalid, illegal or unenforceable provision had never been contained herein.

[Signature Pages Follow]

The undersigned has executed this Agreement as of the date first set forth above.	
	THE COMPANY:
	SIERRA ONCOLOGY, INC.
	Ву:
	(Signature) Name: Sukhi Jagpal

Title: Chief Financial Officer

PURCHASER:
GILEAD SCIENCES, INC.
(Signature) Name: Title:

The undersigned has executed this Agreement as of the date first set forth above.

**EXHIBIT A - Form of Warrant** 

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR UNDER THE SECURITIES LAWS OF CERTAIN STATES. THESE SECURITIES MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED EXCEPT AS PERMITTED UNDER THE ACT AND APPLICABLE STATE SECURITIES LAWS IN ACCORDANCE WITH APPLICABLE REGISTRATION REQUIREMENTS OR AN EXEMPTION THEREFROM. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE ISSUER THAT SUCH OFFER, SALE OR TRANSFER, PLEDGE OR HYPOTHECATION OTHERWISE COMPLIES WITH THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS.

Sierra Oncology, Inc.
Warrant to Purchase Common Stock
Warrant No.: []
Date of Issuance: [] [], 20[] (" <b>Issuance Date</b> ")
Sierra Oncology, Inc., a Delaware corporation (the "Company"), hereby certifies that, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Gilead Sciences, Inc, the registered holder hereof or its permitted assigns (the "Holder"), is entitled, subject to the terms set forth below, to purchase from the Company, at the Exercise Price (as defined below) then in effect, upon surrender of this Warrant to Purchase Common Stock (including any Warrants to Purchase Common Stock issued in exchange, transfer or replacement hereof, this "Warrant"), at any time or times on or after the Issuance Date (the "Exercisability Date"), but not after 5:00 p.m., New York time, on the Expiration
Date (as defined below), a number of fully paid and non-assessable shares of Common Stock (the "Warrant Shares") equal to  [
Exercise(s)), with any fractional share being rounded to the nearest whole share. Except as otherwise defined herein, capitalized terms in this Warrant shall have the meanings set forth in Section 14 of this Warrant. This Warrant is the Warrant to Purchase Common Stock issued pursuant to that certain Security Purchase Agreement, dated as of [] [], 20[] (the "Subscription Date"), by and between the Company and the Holder (the "SPA").

## 1. Exercise of Warrant.

a. Mechanics of Exercise. Subject to the terms and conditions hereof, this Warrant may be exercised by the Holder on any day on or after the Exercisability Date, in whole or in part (subject to adjustment in accordance herewith)), by (i) delivery of a written notice, in the form attached hereto as Exhibit A (the "Exercise Notice"), of the Holder's election to exercise this Warrant and (ii)(A) payment to the Company of an amount equal to the applicable Exercise Price *multiplied by* the number of Warrant Shares as to which this Warrant is being exercised (the "Aggregate Exercise Price") in cash or by wire transfer of immediately available funds, or (B) by notifying the Company that this Warrant is being exercised pursuant to a Cashless Exercise (as defined in Section 1(c)). Execution and delivery of the Exercise Notice with respect to less than all of the Warrant Shares shall have the same effect as cancellation of the original Warrant and issuance of a new Warrant evidencing the right to purchase the remaining number of Warrant Shares. On or before the second (2nd) Business Day following the date on which the Company has received the Exercise Notice (or notice of a Cashless Exercise) (the "Exercise Delivery Documents"), the Company shall transmit by facsimile an acknowledgment of confirmation of receipt of the Exercise Delivery Documents to the Holder and the Company's transfer agent (the "Transfer Agent"). On or before the third (3rd) Business Day following the date on which the Company has received all of the Exercise Delivery Documents, but subject to the prior receipt by the Company of the Aggregate Exercise Price (the "Share Delivery Date"), the Company shall (X) provided that the Transfer Agent is participating in The Depository Trust Company ("DTC") Fast Automated Securities Transfer Program, upon the request of the Holder, credit such aggregate number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with DTC through its Direct Registration System, or (Y) if the Transfer Agent is not participating in the DTC Fast Automated Securities Transfer Program, issue and dispatch by overnight courier to the address as

specified in the Exercise Notice, a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of shares of Common Stock to which the Holder is entitled pursuant to such exercise. The Holder acknowledges and agrees that the certificate or book entry evidencing such Warrant Shares delivered upon such exercise, if required by applicable securities law, will be bear the restrictive legend contemplated by Section 13(a) and be subject to restrictions on resale under applicable securities law. Upon delivery of the Exercise Delivery Documents and, if applicable, the Aggregate Exercise Price, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date such Warrant Shares are credited to the Holder's DTC account or the date of delivery of the certificates evidencing such Warrant Shares, as the case may be. If this Warrant is submitted in connection with any exercise pursuant to this Section 1(a) and the number of Warrant Shares represented by this Warrant submitted for exercise is greater than the number of Warrant Shares being acquired upon an exercise, then the Company shall as soon as practicable and in no event later than five (5) Business Days after any exercise and at its own expense, issue a new Warrant (in accordance with Section 6(d)) representing the right to purchase the number of Warrant Shares purchasable immediately prior to such exercise under this Warrant, less the number of Warrant Shares with respect to which this Warrant is exercised. No fractional shares of Common Stock are to be issued upon the exercise of this Warrant, but rather the number of shares of Common Stock to be issued shall be rounded to the nearest whole number. The Company shall pay any and all taxes which may be payable with respect to the issuance and delivery of Warrant Shares upon exercise of this Warrant; provided, however, that the Company shall not be required to pay any tax that may be payable in respect of any transfer involved in the registration of Warrants or Warrant Shares in a name other than that of the Holder. It is understood and agreed by the Holder that Holder shall be responsible for all other tax liabilities that may arise as a result of holding or transferring this Warrant or receiving Warrant Shares upon exercise thereof.

- b. Exercise Price. For purposes of this Warrant, "Exercise Price" means \$[\_\_\_\_\_] subject to adjustment as provided herein.
- c. <u>Cashless Exercise</u>. The Holder may, in its sole discretion, exercise this Warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the Aggregate Exercise Price, elect instead to receive upon such exercise the "Net Number" of shares of Common Stock determined according to the following formula (a "Cashless Exercise"):

Net Number = 
$$(\underline{A \times B}) - (\underline{A \times C})$$

For purposes of the foregoing formula:

- A = the total number of shares with respect to which this Warrant is then being exercised (which shall include both the number of Warrant Shares issued to the Holder and the number of Warrant Shares subject to the portion of this Warrant being cancelled in payment of the Exercise Price).
- B = the Closing Sale Price of the shares of Common Stock immediately preceding the time of the Exercise Notice (the "Fair Market Value").
- C = the Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

If on the Expiration Date the Net Number exceeds zero, this Warrant shall be deemed to be automatically exercised via a Cashless Exercise pursuant to this Section 1(c).

d. <u>Rule 144</u>. For purposes of Rule 144 promulgated under the Securities Act of 1933, as amended (the "**Securities Act**"), as in effect on the date hereof, it is intended that the Warrant Shares issued in a Cashless Exercise shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued.

- e. <u>Disputes</u>. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares, the Company shall promptly issue to the Holder the number of Warrant Shares that are not disputed.
- f. <u>Company's Failure to Timely Deliver Securities</u>. If the Company shall fail for any reason or for no reason to issue to the Holder on the Share Delivery Date in compliance with the terms of this Section 1, a certificate for the number of shares of Common Stock to which the Holder is entitled and register such shares of Common Stock on the Company's share register or to credit the Holder's balance account with DTC for such number of shares of Common Stock to which the Holder is entitled upon the Holder's exercise of this Warrant, then the Holder shall be entitled, but not required, to rescind the previously submitted Exercise Notice and the Company shall return all consideration paid by Holder for such shares upon such rescission. Notwithstanding anything herein to the contrary, the Company shall not be required to make any cash payments to the Holder in lieu of issuance of the Warrant Shares.
- g. <u>Blocker Provision</u>. Notwithstanding anything contained herein to the contrary, for so long as the Common Stock is an equity security as defined in Rule 13d-1(i) promulgated pursuant to the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Company shall not effect any exercise of this Warrant for shares of Common Stock, and the Holder shall not have the right to exercise any portion of this Warrant for shares of Common Stock to the extent that after giving effect to the issuance of shares of Common Stock upon such exercise, as set forth in the applicable Exercise Notice, any of the Holder, another person having beneficial ownership of such shares of Common Stock or any group of which the Holder or any such other person is a member (any such other person or group, an "Additional Beneficial Owner"), would beneficially own in excess of 9.99% of the outstanding shares of Common Stock (such limitation, the "Conversion Cap"). The Conversion Cap may be terminated by the Holder upon 61 days' advance written notice to the Company. Nothing in this Section 1(g) shall limit the right of the Holder to elect any cashless settlement of this Warrant pursuant to Section 1(c)

Upon the request of the Holder, the Company shall promptly, and in any event within two (2) Trading Days of such request, confirm to the Holder the number of shares of Common Stock then outstanding. At the time of delivery of any Exercise Notice, the Holder shall certify to the Company that neither the Holder nor any Additional Beneficial Owner would beneficially own in excess of 9.99% of the outstanding shares of Common Stock upon giving effect to such Exercise Notice. For purposes of this Section 1(g), the number of shares of Common Stock beneficially owned by any person shall be calculated in accordance with Rule 16a-1(a)(1) promulgated under the Exchange Act, or any successor rule, in each case giving effect to the Conversion Cap. In addition, "group" as used in this Section 1(g) has the same meaning as in Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder.

h. Reservation and Issuance of Shares. The Company shall at all times reserve and keep available out of its authorized but unissued Common Stock or other securities constituting Warrant Shares, solely for the purpose of issuance upon the exercise of this Warrant, the maximum number of Warrant Shares issuable upon the exercise of this Warrant, and the par value per Warrant Share shall at all times be less than or equal to the applicable Exercise Price. The Company shall not increase the par value of any Warrant Shares receivable upon the exercise of this Warrant above the Exercise Price then in effect, and shall take all such actions as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and non-assessable shares of Common Stock upon the exercise of this Warrant. The Company shall take all such actions as may be necessary to ensure that all such Warrant Shares are issued without violation by the Company of any applicable law or governmental regulation, or any contract or agreement to which the Company is party (including not being subject to any preemptive, co-sale, right of first refusal or any other similar rights of the stockholders of the Company or any other person that have not been waived or satisfied), or any liens or encumbrances or result in the triggering of any anti-dilution or other similar rights that have not been waived or satisfied, or any requirements of any securities exchange upon which shares of Common Stock or other securities constituting Warrant Shares may be listed at the time of such exercise (except for official notice of issuance which shall be immediately delivered by the Company upon each such issuance). The Company shall cause the Warrant Shares are listed at the time of such exercise.

- 2. Adjustment of Exercise Price and Number of Warrant Shares. If the Company at any time on or after the Subscription Date subdivides (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise) one or more classes of its outstanding shares of Common Stock into a greater number of shares, the Exercise Price in effect immediately prior to such subdivision will be proportionately reduced and the number of Warrant Shares will be proportionately increased. If the Company at any time on or after the Subscription Date combines (by any stock split, reverse stock split, stock consolidation, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise) one or more classes of its outstanding shares of Common Stock into a smaller number of shares, the Exercise Price in effect immediately prior to such combination will be proportionately increased and the number of Warrant Shares will be proportionately decreased. Any adjustment under this Section 2 shall become effective at the close of business on the date the subdivision or combination becomes effective.
- 3. <u>Rights Upon Distribution of Assets</u>. If the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to all holders of shares of Common Stock for no consideration, by way of return of capital or otherwise (including, without limitation, any dividend or distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction (other than stock or securities in which an adjustment is being made pursuant to Section 2 hereof)) (a "**Distribution**"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant immediately before the date on which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution.
- 4. <u>Fundamental Transactions</u>. In the event of a Fundamental Transaction, either (a) the Holder shall exercise this Warrant in full with respect to all remaining Warrant Shares for which this Warrant is then exercisable and such exercise or conversion will be deemed effective immediately prior to the consummation of such Fundamental Transaction or (b) if the Holder elects not to exercise this Warrant, and the Fair Market Value of one Warrant Share would be greater than the Exercise Price in effect on such date immediately prior to such Fundamental Transaction, and Holder has not exercised this Warrant as to all Warrant Shares, then this Warrant shall automatically be deemed to be Cashless Exercised pursuant to Section 1(c) above as to all Warrant Shares effective immediately prior to and contingent upon the consummation of a Fundamental Transaction. In the event of a Fundamental Transaction where the Fair Market Value of one Warrant Share would be less than the Exercise Price in effect immediately prior to such Fundamental Transaction, then this Warrant will expire immediately prior to the consummation of such Fundamental Transaction.

#### 5. [Reserved].

6. Warrant Holder Not Deemed a Stockholder. Except as otherwise specifically provided herein (including the adjustments in Sections 1, 2, 3 and 4), the Holder, solely in such person's capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in such person's capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which such person is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

#### 7. Certificate as to Adjustment; Notices of Events.

- a. <u>Certificate as to Adjustment</u>. As promptly as reasonably practicable following any adjustment of the Exercise Price, but in any event not later than fifteen (15) Business Days thereafter, the Company shall furnish to the Holder a notice setting forth in reasonable detail such adjustment and the facts upon which it is based and certifying the calculation thereof. As promptly as reasonably practicable following the receipt by the Company of a written request by the Holder, but in any event not later than fifteen (15) Business Days thereafter, the Company shall furnish to the Holder notice of the Exercise Price then in effect and the number of Warrant Shares or the amount, if any, of other shares of stock, securities or assets then issuable upon exercise of this Warrant.
  - b. Notices of Events. In the event that the Company:
- (i) shall take a record of the holders of its Common Stock for, or enter into or consummate, a transaction that would result in an adjustment in the Exercise Price and/or the number of Warrant Shares issuable upon exercise of this Warrant,
- (ii) shall take a record of the holders of its Common Stock (or other capital stock or securities at the time issuable upon exercise of this Warrant) for the purpose of entitling or enabling them to receive any dividend or other distribution, to vote at a meeting (or by written consent), to receive any right to subscribe for or purchase any shares of capital stock of any class or any other securities, or to receive any other security; or
  - (iii) shall approve or consummate the voluntary or involuntary dissolution, liquidation or winding-up of the Company,

then, and in each such case, the Company shall send or cause to be sent to the Holder a notice describing such event, which notice shall be sent at least five (5) Business Days prior to such event and shall specify: (a) in the case of clauses (i) and (iii), the effective date on which such transaction is proposed to take place, and the date, if any is to be fixed, as of which the books of the Company shall close or a record shall be taken with respect to which the holders of record of Common Stock (or such other capital stock or securities at the time issuable upon exercise of this Warrant) shall be entitled to exchange their shares of Common Stock (or such other capital stock or securities) for securities or other property deliverable upon such transaction, and the amount per share and character of such exchange applicable to this Warrant and the Warrant Shares; and (b) in the case of clause (ii), the record date for such dividend, distribution, meeting or consent or other right or action, and a description of such dividend, distribution or other right or action to be taken at such meeting or by written consent. The Holder acknowledges that if any such notice given pursuant to this Section 7.b. would constitute material nonpublic information, the Company shall not be required to give the Holder any such notice until the occurrence of such event has been announced publicly by the Company by way of a press release or filing with the Securities and Exchange Commission.

#### 8. Reissuance of Warrants.

- a. <u>Transfer of Warrant</u>. If this Warrant is to be transferred, the Holder shall surrender this Warrant to the Company together with such other information, documents and instruments related to such transfer that the Company shall reasonably request (including without limitation those required by the SPA or Section 13 hereof), whereupon the Company will forthwith issue and deliver upon the order of the Holder a new Warrant (in accordance with Section 8(d)), registered as the Holder may request, representing the right to purchase the number of Warrant Shares being transferred by the Holder and, if less than the total number of Warrant Shares then underlying this Warrant is being transferred, a new Warrant (in accordance with Section 8(d)) to the Holder representing the right to purchase the number of Warrant Shares not being transferred.
- b. <u>Lost, Stolen or Mutilated Warrant</u>. Upon receipt by the Company of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant, and, in the case of loss, theft or destruction, of any indemnification undertaking by the Holder to the Company in customary form and, in the case of mutilation, upon surrender and cancellation of this Warrant, the Company shall execute and deliver to the Holder a new Warrant (in accordance with Section 8(d)) representing the right to purchase the Warrant Shares then underlying this Warrant.
- c. Exchangeable for Multiple Warrants. This Warrant is exchangeable, upon the surrender hereof by the Holder at the principal office of the Company, for a new Warrant or Warrants (in accordance with Section 8(d)) representing in the aggregate the right to purchase the number of Warrant Shares then underlying this Warrant, and each such new Warrant will represent the right to purchase such portion of such Warrant Shares as is designated by the Holder at the time of such surrender; provided, however, that no Warrants for fractional shares of Common Stock shall be given.

- d. <u>Issuance of New Warrants</u>. Whenever the Company is required to issue a new Warrant pursuant to the terms of this Warrant, such new Warrant (i) shall be of like tenor with this Warrant, (ii) shall represent, as indicated on the face of such new Warrant, the right to purchase the Warrant Shares then underlying this Warrant (or in the case of a new Warrant being issued pursuant to Section 8(a) or Section 8(c), the Warrant Shares designated by the Holder which, when added to the number of shares of Common Stock underlying the other new Warrants issued in connection with such issuance, does not exceed the number of Warrant Shares then underlying this Warrant), (iii) shall have an issuance date, as indicated on the face of such new Warrant which is the same as the Issuance Date, and (iv) shall have the same rights and conditions as this Warrant.
- 9. <u>Notices</u>. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and in English and shall be deemed given and effective if (a) delivered by hand or by overnight courier with tracking capabilities, (b) mailed postage prepaid by first class, registered, or certified mail, or (c) delivered by facsimile or electronic mail, and followed by a confirmation copy delivered via either of the methods set forth in Sections 9(a) and (b). The address, facsimile numbers and email addresses for such communications shall be:

If to the Company:

Sierra Oncology, Inc. Attention: Chief Financial Officer c/o 2150 – 885 West Georgia Street Vancouver, British Columbia, Canada Telephone: 604-558-6536 Fax: [

Email: sjagpal@sierraoncology.com

If to the Holder, to its address, facsimile number or email address set forth herein or on the books and records of the Company.

Or, in each of the above instances, to such other address, facsimile number or email address as the recipient party has specified by written notice given to each other party at least five (5) days prior to the effectiveness of such change.

- 10. <u>Transfer Agent Fees</u>. The Company shall pay all fees of its transfer agent in connection with the transactions contemplated by this Agreement, the exercise of this Warrant and the issuance of the Warrant Shares.
- 11. <u>Amendment and Waiver</u>. Except as otherwise provided herein, the provisions of this Warrant may be amended and the Company may take any action herein prohibited, or omit to perform any action herein required to be performed by it, only if the Company has obtained the prior written consent of the Holder.
- 12. <u>Governing Law</u>. This Warrant shall be governed by and construed and enforced in accordance with, and all questions concerning the construction, validity, interpretation and performance of this Warrant shall be governed by, the internal laws of the State of Delaware, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of Delaware or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of Delaware.
- 13. <u>Construction; Headings</u>. This Warrant shall be deemed to be jointly drafted by the Company and the Holder and shall not be construed against any person as the drafter hereof. The headings of this Warrant are for convenience of reference and shall not form part of, or affect the interpretation of, this Warrant.

- 14. <u>Remedies, Other Obligations, Breaches and Injunctive Relief.</u> The remedies provided in this Warrant shall be cumulative and in addition to all other remedies available under this Warrant, at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the right of the Holder to pursue actual damages for any failure by the Company to comply with the terms of this Warrant.
- 15. Restrictions on Transfer of this Warrant and Warrant Shares; Compliance with Securities Laws.
  - a. Transfer Restrictions. This Warrant shall not be transferred, except to an affiliate of the Holder, without the written consent of the Company.
- b. <u>Securities Law Legend</u>. Each certificate, instrument or book entry evidencing the Securities shall (unless otherwise permitted by the provisions of this Warrant) be notated with a legend substantially similar to the following (in addition to any legend required by state securities laws):

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR UNDER THE SECURITIES LAWS OF CERTAIN STATES. THESE SECURITIES MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED EXCEPT AS PERMITTED UNDER THE ACT AND APPLICABLE STATE SECURITIES LAWS IN ACCORDANCE WITH APPLICABLE REGISTRATION REQUIREMENTS OR AN EXEMPTION THEREFROM. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE ISSUER THAT SUCH OFFER, SALE OR TRANSFER, PLEDGE OR HYPOTHECATION OTHERWISE COMPLIES WITH THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS.

- c. <u>Instructions Regarding Transfer Restrictions</u>. The Holder consents to the Company making a notation on its records and giving instructions to any transfer agent in order to implement the restrictions on transfer established in this Section 15.
- d. Removal of Legend. The legend referring to federal and state securities laws set forth on the first page of this Warrant and the legend identified in Section 15(b) notated on any certificate or book entry evidencing the Warrant Shares and the stock transfer instructions and record notations with respect to such securities shall be removed, and the Company shall issue a Warrant or certificate, as applicable, without such legend to the holder of such securities (to the extent the securities are certificated), if (i) such securities are registered under the Securities Act, or (ii) such holder provides the Company with an opinion of counsel reasonably acceptable to the Company to the effect that such legend may be removed from such securities or a sale or transfer of such securities may be made without registration, qualification or legend.
- 16. Certain Definitions. For purposes of this Warrant, the following terms shall have the following meanings:
- a. "Business Day" means any day other than any Saturday, any Sunday, any day which is a federal legal holiday in the United States, any day on which banking institutions in The City of New York or the State of New York are authorized or required by law or other governmental action to close or any day between and including Christmas Day and New Year's Day.
- b. "Closing Sale Price" means, as of any particular date: (a) the closing sales price of the Common Stock for such day on the Principal Market or such other U.S. securities exchange on which the Common Stock may at the time be listed, or if not then listed on a U.S. securities exchange then on such foreign securities exchange on which the Common Stock may at the time be listed; (b) if on any such day the Common Stock is not listed on a securities exchange, the closing sales price of the Common Stock as quoted on the OTC Bulletin Board, the OTC Marketplace or similar quotation system or association for such day; (c) if there have been no sales of the Common Stock on the OTC Bulletin Board, the OTC Marketplace or similar quotation system or association at lowest asked prices for the Common Stock quoted on the OTC Bulletin Board, the OTC Marketplace or similar quotation system or association at the end of such day; in each case, averaged over ten (10) consecutive Trading Days ending on the Trading Day immediately prior to the day as of which "Fair Market Value" is being determined; or (d) if at any time the Common Stock is not listed on any securities exchange or quoted on the OTC Bulletin Board, the OTC Marketplace or similar quotation system or association, the "Fair Market Value" of the Common Stock shall be the fair market value per share as determined jointly by the Board of Directors of the Company and the Holder; provided, that if the Board of Directors of the Company and the Holder

are unable to agree on the fair market value per share of the Common Stock within a reasonable period of time (not to exceed thirty (30) days from the Company's receipt of the notice of exercise of this Warrant), such fair market value shall be determined by a nationally recognized investment banking, accounting or valuation firm jointly selected by the Board of Directors of the Company and the Holder. The determination of such firm shall be final and conclusive, and the fees and expenses of such valuation firm shall be borne equally by the Company and the Holder. In determining the Fair Market Value of the Common Stock, an orderly sale transaction between a willing buyer and a willing seller shall be assumed, using valuation techniques then prevailing in the securities industry without regard to the lack of liquidity of the Common Stock due to any restrictions (contractual or otherwise) applicable thereto or any discount for minority interests and assuming full disclosure of all relevant information and a reasonable period of time for effectuating such sale.

- c. "Common Stock" means (i) the Company's shares of Common Stock, par value \$0.001 per share, and (ii) any share capital into which such Common Stock shall have been changed, converted or exchanged any share capital resulting from a reclassification or recapitalization of such Common Stock.
- d. "Expiration Date" means the date five (5) years after the Issuance Date. If such date falls on a day other than a Business Day or on which trading does not take place on the Principal Market (a "Holiday"), then the Expiration Date shall be the next date that is a Business Day and is not a Holiday.
- e. "Fundamental Transaction" means (i) the consolidation of the Company with, or the merger of the Company with or into, another "person" (as such term is used in Rule 13d-3 and Rule 13d-5 of the Exchange Act), or the sale, lease, transfer, conveyance or other disposition, in one or a series of related transactions, of all or substantially all of the assets of the Company and its subsidiaries taken as a whole, or the consolidation of another "person" with, or the merger of another "person" into, the Company, other than in each case pursuant to a transaction in which the "persons" that "beneficially owned" (as such term is defined in Rule 13d-3 and Rule 13d-5 under the Exchange Act), directly or indirectly, the Voting Shares (as defined below) of the Company immediately prior to the transaction "beneficially own", directly or indirectly, Voting Shares representing at least a majority of the total voting power of all outstanding classes of voting stock of the surviving or transferee person; (ii) the adoption by the Company of a plan relating to the liquidation or dissolution of the Company; or (iii) the consummation of any transaction (including, without limitation, any merger or consolidation) the result of which is that any "person" becomes the "beneficial owner" directly or indirectly, of more than 50% of the Voting Shares of the Company (measured by voting power rather than the number of shares.
  - f. "Principal Market" means The Nasdaq Global Market.
- g. "Trading Day" means any day on which the Common Stock is traded on the Principal Market, or, if the Principal Market is not the principal trading market for the Common Stock, then on the principal securities exchange or securities market on which the Common Stock are then traded or quoted; <u>provided</u> that "Trading Day" shall not include any day on which the Common Stock are scheduled to trade on such exchange or market for less than 4.5 hours or any day that the Common Stock are suspended from trading during the final hour of trading on such exchange or market (or if such exchange or market does not designate in advance the closing time of trading on such exchange or market, then during the hour ending at 4:00:00 p.m., New York time).

[Signature Page Follows]

above.	
	SIERRA ONCOLOGY, INC.
	By: (Signature) Name: Sukhi Jagpal Title: Chief Financial Officer
Acknowledged and agreed	
GILEAD SCIENCES, INC.	
(Signature) Name:	
TITIE:	

IN WITNESS WHEREOF, the Company has caused this Warrant to Purchase Common Stock to be duly executed as of the Issuance Date set out

[Signature Page to Warrant to Purchase Common Stock]

# **EXHIBIT A**

# EXERCISE NOTICE

# TO BE EXECUTED BY THE REGISTERED HOLDER TO EXERCISE THIS

# WARRANT TO PURCHASE COMMON STOCK

# SIERRA ONCOLOGY, INC.

The undersigned holder hereby exercises the right to purchase of the shares of Common Stock ("Warrant Shares") of Sierra Oncology, Inc., a Delaware corporation (the "Company"), evidenced by the attached Warrant to Purchase Common Stock (the "Warrant"). Capitalized terms used herein and not otherwise defined shall have the respective meanings set forth in the Warrant.
1. Form of Exercise Price. The Holder intends that payment of the Exercise Price shall be made as:
a " <u>Cash Exercise"</u> with respect to Warrant Shares; and/or
a " <u>Cashless Exercise</u> " with respect to Warrant Shares.
2. Payment of Exercise Price. In the event that the holder has elected a Cash Exercise with respect to some or all of the Warrant Shares to be issued pursuant hereto, the holder shall pay the Aggregate Exercise Price in the sum of \$ to the Company in accordance with the terms of the Warrant.
3. Delivery of Warrant Shares. The Company shall deliver to the Holder Warrant Shares in accordance with the terms of the Warrant.
4. Beneficial Ownership Confirmation. For so long as Section 1(g) is applicable and has not been terminated by the Holder, the Holder confirms that neither the Holder nor any Additional Beneficial Owner will beneficially own in excess of 9.99% of the outstanding shares of Common Stock upon giving effect to this Exercise Notice.
Dated:
Name of Holder:
By:
Name:
Title:

#### DESCRIPTION OF CAPITAL STOCK

#### General

Our authorized capital stock consists of 500,000,000 shares of common stock, \$0.001 par value per share, and 10,000,000 shares of undesignated preferred stock, \$0.001 par value per share. The following description summarizes the most important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our restated certificate of incorporation and restated bylaws, which are included as exhibits to our most recent Annual Report on Form 10-Kand to the applicable provisions of Delaware law.

#### Common Stock

### **Dividend Rights**

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine.

### **Voting Rights**

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. We have not provided for cumulative voting for the election of directors in our restated certificate of incorporation. Accordingly, holders of a majority of the shares of our common stock are able to elect all of our directors. Our restated certificate of incorporation establishes a classified board of directors, divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

#### No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions.

#### Right to Receive Liquidation Distributions

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

# **Registration Rights**

Certain of our common stock holders are entitled to certain registration rights with respect to the sale of such shares under the Securities Act. We refer to these shares as registrable securities. These rights are provided under the terms of an amended and restated investors' rights agreement between us and the holders of these shares, which was entered into in connection with our preferred stock financings, and include demand registration rights, short-form registration rights and piggyback registration rights. In any registration made pursuant to such amended and restated investors' rights agreement, all fees, costs and expenses of underwritten registrations, including fees and disbursements of one special counsel to the selling stockholders not to exceed \$30,000, will be borne by us and all selling expenses, including estimated underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

The registration rights terminate on July 21, 2020 or, with respect to any particular stockholder, at such time as such stockholder can sell all of its shares in a single transaction pursuant to Rule 144 promulgated under the Securities Act.

#### **Demand Registration Rights**

Under the terms of the amended and restated investor rights agreement, if we receive a written request from the holders of at least 25% of the registrable securities then outstanding that we file a registration statement under the Securities Act with an anticipated aggregate price to the public of at least \$5.0 million, we will be obligated to notify all holders of registrable securities of the written request and use commercially reasonable efforts to effect the registration of all registrable securities that holders request to be registered. We are required to effect no more than two registration statements that are declared or ordered effective, subject to certain exceptions. We may postpone the filing of a registration statement for up to 90 days once in a 12-month period if in the good-faith judgment of our board of directors such registration would be detrimental to us.

# Piggyback Registration Rights

If we register any of our securities for public sale in an offering pursuant to this prospectus, we are required to afford each holder of registrable securities an opportunity to include all or part of the holder's registrable securities in such registration. Each holder desiring to include all or any part of the registrable securities held by it in any such registration statement is required to notify us within 10 business days of being notified by us in writing of the registration. This right does not apply to registration statements relating to demand registrations, for Form S-3 registrations, employee benefit plans, a corporate reorganization or other transaction under Rule 145 of the Securities Act, or stock issued upon conversion of debt securities. The underwriter of any underwritten offering will have the right to limit, due to marketing factors, the number of shares registered by these holders to 30% of the total shares covered by the registration statement. In no event will shares of any other selling stockholder be included in such registration that would reduce the number of shares which may be included by these holders without the consent of the holders of at least two-thirds (66 2/3%) of the registrable securities proposed to be sold in the offering.

### Form S-3 Registration Rights

The holders of registrable securities can request that we register all or a portion of their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and the aggregate price to the public of the shares offered is at least \$5.0 million. The holders of registrable securities may require us to effect at most two registration statements on Form S-3 in any 12-month period. We may postpone the filing of a registration statement for up to 90 days once in a 12-month period if in the good-faith judgment of our board of directors such registration would be detrimental to us or if we notify holders within 30 days of making the Form S-3 registration request that we intend to make a public offering within 90 days.

#### **Anti-Takeover Provisions**

The provisions of Delaware law, our restated certificate of incorporation and our restated bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

#### **Delaware Law**

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, regulating corporate takeovers. In general, DGCL Section 203 prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or 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, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

• at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction or series of transactions together resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that DGCL Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

### Restated Certificate of Incorporation and Restated Bylaws Provisions

Our restated certificate of incorporation and our restated bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our company, including the following:

- **Board of Directors Vacancies.** Our restated certificate of incorporation and restated bylaws authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors is permitted to be set only by a resolution adopted by a majority vote of our entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.
- Classified Board. Our restated certificate of incorporation and restated bylaws provide that our board of directors is classified into three
  classes of directors, each with staggered three-year terms. A third party may be discouraged from making a tender offer or otherwise
  attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a
  classified board of directors.
- Stockholder Action; Special Meetings of Stockholders. Our restated certificate of incorporation provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our restated bylaws. Further, our restated bylaws and restated certificate of incorporation provide that special meetings of our stockholders may be called only by a majority of our board of directors, the chairman of our board of directors, our Chief Executive Officer or our President, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.
- Advance Notice Requirements for Stockholder Proposals and Director Nominations. Our restated bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our restated bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.
- **No Cumulative Voting.** The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our restated certificate of incorporation and restated bylaws do not provide for cumulative voting.
- **Directors Removed Only for Cause.** Our restated certificate of incorporation provides that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least two-thirds of our outstanding common stock.
- **Amendment of Charter Provisions.** Any amendment of the above provisions in our restated certificate of incorporation requires approval by holders of at least two-thirds of our outstanding common stock.
- **Issuance of Undesignated Preferred Stock.** Our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or other means.

• Choice of Forum. Our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, restated certificate of incorporation or our restated bylaws; any action to interpret, apply, enforce or determine the validity of our restated certificate of incorporation or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

### **Exchange Listing**

Our common stock is listed on The Nasdaq Global Market under the symbol "SRRA."

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is American Stock Transfer and Trust Company, LLC.

#### SIERRA ONCOLOGY, INC.

#### 2015 EQUITY INCENTIVE PLAN

#### As amended on January 21, 2020

1. <u>PURPOSE</u>. The purpose of this Plan is to provide incentives to attract, retain and motivate eligible persons whose present and potential contributions are important to the success of the Company, and any Parents and Subsidiaries that exist now or in the future, by offering them an opportunity to participate in the Company's future performance through the grant of Awards. Capitalized terms not defined elsewhere in the text are defined in Section 28.

### 2. SHARES SUBJECT TO THE PLAN.

- **2.1.** Number of Shares Available. Subject to Sections 2.6 and 21 and any other applicable provisions hereof, the total number of Shares reserved and available for grant and issuance pursuant to this Plan as of the Amendment Effective Date (as defined below) is four million three hundred twelve thousand five hundred (4,312,500) Shares, plus (a) any reserved shares not issued or subject to outstanding grants under the Plan as of immediately prior to the Amendment Effective Date, (b) shares that are subject to stock options or other awards granted under the Company's 2008 Stock Plan (the "**Prior Plan**") on the Amendment Effective Date that cease to be subject to such stock options or other awards by forfeiture or otherwise after the Amendment Effective Date, (c) shares issued under the Prior Plan before or after the Amendment Effective Date pursuant to the exercise of stock options that are, after the Amendment Effective Date, forfeited, (d) shares issued under the Prior Plan that are repurchased by the Company at the original issue price and (e) shares that are subject to stock options or other awards under the Prior Plan that are used to pay the exercise price of an option or withheld to satisfy the tax withholding obligations related to any award.
- 2.2. Lapsed, Returned Awards. Shares subject to Awards, and Shares issued under the Plan under any Award, will again be available for grant and issuance in connection with subsequent Awards under this Plan to the extent such Shares: (a) are subject to issuance upon exercise of an Option or SAR granted under this Plan but which cease to be subject to the Option or SAR for any reason other than exercise of the Option or SAR; (b) are subject to Awards granted under this Plan that are forfeited or are repurchased by the Company at the original issue price; (c) are subject to Awards granted under this Plan that otherwise terminate without such Shares being issued; or (d) are surrendered pursuant to an Exchange Program. To the extent an Award under the Plan is paid out in cash rather than Shares, such cash payment will not result in reducing the number of Shares available for issuance under the Plan. Shares used to pay the exercise price of an Award or withheld to satisfy the tax withholding obligations related to an Award will become available for future grant or sale under the Plan. For the avoidance of doubt, Shares that otherwise become available for grant and issuance because of the provisions of this Section 2.2 shall not include Shares subject to Awards that initially became available because of the substitution clause in Section 21.2 hereof.
- **2.3.** <u>Minimum Share Reserve</u>. At all times the Company shall reserve and keep available a sufficient number of Shares as shall be required to satisfy the requirements of all outstanding Awards granted under this Plan.
- **2.4.** <u>Automatic Share Reserve Increase</u>. The number of Shares available for grant and issuance under the Plan shall be increased on January 1, of each of the calendar years 2016 through 2025, by the lesser of (a) four (4%) of the number of Shares issued and outstanding on each December 31 immediately prior to the date of increase or (b) such number of Shares determined by the Board.
  - 2.5. <u>Limitations</u>. No more than twelve million five hundred thousand (12,500,000) Shares shall be issued pursuant to the exercise of ISOs.
- **2.6.** <u>Adjustment of Shares</u>. If the number of outstanding Shares is changed by a stock dividend, extraordinary dividends or distributions (whether in cash, shares or other property, other than a regular cash dividend) recapitalization, stock split, reverse stock split, subdivision, combination, reclassification, spin-off or similar change in the capital structure of the Company, without consideration, then (a) the number of Shares reserved for issuance and future grant under the Plan set forth in Section 2.1, including shares reserved under sub-clauses (a)-(e) of Section 2.1, (b) the Exercise Prices of and number of Shares subject to outstanding Options and SARs, (c) the number of Shares subject to other outstanding Awards, and (d) the maximum number of shares that may be issued as ISOs set forth in Section 2.5 shall be proportionately adjusted, subject to any required action by the Board or the stockholders of the Company and in compliance with applicable securities laws; provided that fractions of a Share will not be issued.

**3. ELIGIBILITY**. ISOs may be granted only to Employees. All other Awards may be granted to Employees, Consultants, Directors and Non-Employee Directors; <u>provided</u> such Consultants, Directors and Non-Employee Directors render bona fide services not in connection with the offer and sale of securities in a capital-raising transaction.

#### 4. ADMINISTRATION.

- **4.1.** <u>Committee Composition; Authority.</u> This Plan will be administered by the Committee or by the Board acting as the Committee. Subject to the general purposes, terms and conditions of this Plan, and to the direction of the Board, the Committee will have full power to implement and carry out this Plan, except, however, the Board shall establish the terms for the grant of an Award to Non-Employee Directors. The Committee will have the authority to:
  - (a) construe and interpret this Plan, any Award Agreement and any other agreement or document executed pursuant to this Plan;
  - (b) prescribe, amend and rescind rules and regulations relating to this Plan or any Award;
  - (c) select persons to receive Awards;
- (d) determine the form and terms and conditions, not inconsistent with the terms of the Plan, of any Award granted hereunder. Such terms and conditions include, but are not limited to, the exercise price, the time or times when Awards may vest and be exercised (which may be based on performance criteria) or settled, any vesting acceleration or waiver of forfeiture restrictions, the method to satisfy tax withholding obligations or any other tax liability legally due and any restriction or limitation regarding any Award or the Shares relating thereto, based in each case on such factors as the Committee will determine;
  - (e) determine the number of Shares or other consideration subject to Awards;
- (f) determine the Fair Market Value in good faith and interpret the applicable provisions of this Plan and the definition of Fair Market Value in connection with circumstances that impact the Fair Market Value, if necessary;
- (g) determine whether Awards will be granted singly, in combination with, in tandem with, in replacement of, or as alternatives to, other Awards under this Plan or any other incentive or compensation plan of the Company or any Parent or Subsidiary of the Company;
  - (h) grant waivers of Plan or Award conditions;
  - (i) determine the vesting, exercisability and payment of Awards;
  - (j) correct any defect, supply any omission or reconcile any inconsistency in this Plan, any Award or any Award Agreement;
  - (k) determine whether an Award has been earned;
  - (l) determine the terms and conditions of any, and to institute any Exchange Program;
  - (m) reduce or waive any criteria with respect to Performance Factors;
- (n) adjust Performance Factors to take into account changes in law and accounting or tax rules as the Committee deems necessary or appropriate to reflect the impact of extraordinary or unusual items, events or circumstances to avoid windfalls or hardships;
- (o) adopt terms and conditions, rules and/or procedures (including the adoption of any subplan under this Plan) relating to the operation and administration of the Plan to accommodate requirements of local law and procedures outside of the United States;
  - (p) make all other determinations necessary or advisable for the administration of this Plan; and
- (q) delegate any of the foregoing to a subcommittee consisting of one or more executive officers pursuant to a specific delegation as permitted by applicable law, including Section 157(c) of the Delaware General Corporation Law.
- **4.2.** Committee Interpretation and Discretion. Any determination made by the Committee with respect to any Award shall be made in its sole discretion at the time of grant of the Award or, unless in contravention of any express term of the Plan or Award, at any later time, and such determination shall be final and binding on the Company and all persons having an interest in any Award under the Plan. Any dispute regarding the interpretation of the Plan or any Award Agreement shall be submitted by the Participant or Company to the Committee for review. The resolution of such a dispute by the Committee shall be final and binding on the Company and the Participant. The Committee may delegate to one or more executive officers the authority to review and resolve disputes with respect to Awards held by Participants who are not Insiders, and such resolution shall be final and binding on the Company and the Participant.

- **4.3.** Section 162(m) of the Code and Section 16 of the Exchange Act. When necessary or desirable for an Award to qualify as "performance-based compensation" under Section 162(m) of the Code the Committee shall include at least two persons who are "outside directors" (as defined under Section 162(m) of the Code) and at least two (or a majority if more than two then serve on the Committee) such "outside directors" shall approve the grant of such Award and timely determine (as applicable) the Performance Period and any Performance Factors upon which vesting or settlement of any portion of such Award is to be subject. When required by Section 162(m) of the Code, prior to settlement of any such Award at least two (or a majority if more than two then serve on the Committee) such "outside directors" then serving on the Committee shall determine and certify in writing the extent to which such Performance Factors have been timely achieved and the extent to which the Shares subject to such Award have thereby been earned. Awards granted to Participants who are subject to Section 16 of the Exchange Act must be approved by two or more "non-employee directors" (as defined in the regulations promulgated under Section 16 of the Exchange Act). With respect to Participants whose compensation is subject to Section 162(m) of the Code, and provided that such adjustments are consistent with the regulations promulgated under Section 162(m) of the Code, the Committee may adjust the performance goals to account for changes in law and accounting and to make such adjustments as the Committee deems necessary or appropriate to reflect the impact of extraordinary or unusual items, events or circumstances to avoid windfalls or hardships, including without limitation (a) restructurings, discontinued operations, extraordinary items, and other unusual or non-recurring charges, (b) an event either not directly related to the operations of the Company or not within the reasonable control of the Company's management, or (c) a change in accounting
- **4.4.** <u>Documentation</u>. The Award Agreement for a given Award, the Plan and any other documents may be delivered to, and accepted by, a Participant or any other person in any manner (including electronic distribution or posting) that meets applicable legal requirements.
- **4.5.** Foreign Award Recipients. Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws and practices in other countries in which the Company and its Subsidiaries operate or have employees or other individuals eligible for Awards, the Committee, in its sole discretion, shall have the power and authority to: (a) determine which Subsidiaries and Affiliates shall be covered by the Plan; (b) determine which individuals outside the United States are eligible to participate in the Plan, which may include individuals who provide services to the Company, Subsidiary or Affiliate under an agreement with a foreign nation or agency; (c) modify the terms and conditions of any Award granted to individuals outside the United States or foreign nationals to comply with applicable foreign laws, policies, customs and practices; (d) establish subplans and modify exercise procedures and other terms and procedures, to the extent the Committee determines such actions to be necessary or advisable (and such subplans and/or modifications shall be attached to this Plan as appendices); provided, however, that no such subplans and/or modifications shall increase the share limitations contained in Section 2.1 hereof; and (e) take any action, before or after an Award is made, that the Committee determines to be necessary or advisable to obtain approval or comply with any local governmental regulatory exemptions or approvals. Notwithstanding the foregoing, the Committee may not take any actions hereunder, and no Awards shall be granted, that would violate the Exchange Act or any other applicable United States securities law, the Code, or any other applicable United States governing statute or law.
- **5. OPTIONS**. An Option is the right but not the obligation to purchase a Share, subject to certain conditions, if applicable. The Committee may grant Options to eligible Employees, Consultants and Directors and will determine whether such Options will be Incentive Stock Options within the meaning of the Code ("**ISOs**") or Nonqualified Stock Options ("**NSOs**"), the number of Shares subject to the Option, the Exercise Price of the Option, the period during which the Option may vest and be exercised, and all other terms and conditions of the Option, subject to the following terms of this section.
- **5.1.** Option Grant. Each Option granted under this Plan will identify the Option as an ISO or an NSO. An Option may be, but need not be, awarded upon satisfaction of such Performance Factors during any Performance Period as are set out in advance in the Participant's individual Award Agreement. If the Option is being earned upon the satisfaction of Performance Factors, then the Committee will: (a) determine the nature, length and starting date of any Performance Period for each Option; and (b) select from among the Performance Factors to be used to measure the performance, if any. Performance Periods may overlap and Participants may participate simultaneously with respect to Options that are subject to different performance goals and other criteria.
- **5.2.** Date of Grant. The date of grant of an Option will be the date on which the Committee makes the determination to grant such Option, or a specified future date. The Award Agreement and a copy of this Plan will be delivered to the Participant within a reasonable time after the granting of the Option.

- **5.3.** Exercise Period. Options may be vested and exercisable within the times or upon the conditions as set forth in the Award Agreement governing such Option; <u>provided</u>, <u>however</u>, that no Option will be exercisable after the expiration of ten (10) years from the date the Option is granted; and <u>provided further</u> that no ISO granted to a person who, at the time the ISO is granted, directly or by attribution owns more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or of any Parent or Subsidiary of the Company ("**Ten Percent Stockholder**") will be exercisable after the expiration of five (5) years from the date the ISO is granted. The Committee also may provide for Options to become exercisable at one time or from time to time, periodically or otherwise, in such number of Shares or percentage of Shares as the Committee determines.
- **5.4.** Exercise Price. The Exercise Price of an Option will be determined by the Committee when the Option is granted; provided that: (a) the Exercise Price of an Option will be not less than one hundred percent (100%) of the Fair Market Value of the Shares on the date of grant and (b) the Exercise Price of any ISO granted to a Ten Percent Stockholder will not be less than one hundred ten percent (110%) of the Fair Market Value of the Shares on the date of grant. Payment for the Shares purchased may be made in accordance with Section 11 and the Award Agreement and in accordance with any procedures established by the Company.
- **5.5.** Method of Exercise. Any Option granted hereunder will be vested and exercisable according to the terms of the Plan and at such times and under such conditions as determined by the Committee and set forth in the Award Agreement. An Option may not be exercised for a fraction of a Share. An Option will be deemed exercised when the Company receives: (a) notice of exercise (in such form as the Committee may specify from time to time) from the person entitled to exercise the Option (and/or via electronic execution through the authorized third-party administrator), and (b) full payment for the Shares with respect to which the Option is exercised (together with applicable withholding taxes). Full payment may consist of any consideration and method of payment authorized by the Committee and permitted by the Award Agreement and the Plan. Shares issued upon exercise of an Option will be issued in the name of the Participant. Until the Shares are issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Shares, notwithstanding the exercise of the Option. The Company will issue (or cause to be issued) such Shares promptly after the Option is exercised. No adjustment will be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Section 2.6 of the Plan. Exercising an Option in any manner will decrease the number of Shares thereafter available, both for purposes of the Plan and for sale under the Option, by the number of Shares as to which the Option is exercised.
- **5.6.** <u>Termination of Service</u>. If the Participant's Service terminates for any reason except for Cause or the Participant's death or Disability, then the Participant may exercise such Participant's Options (only to the extent that such Options are exercisable by the Participant on the date Participant's Service terminates) during the period ending no later than three (3) months after the date Participant's Service terminates (or such shorter or longer time period as may be determined by the Committee, with any exercise beyond three (3) months after the date Participant's Service terminates deemed to be the exercise of an NSO), but in any event no later than the expiration date of the Options.
- (a) <u>Death</u>. If the Participant's Service terminates because of the Participant's death (or the Participant dies within three (3) months after Participant's Service terminates other than for Cause or because of the Participant's Disability), then the Participant's Options may be exercised only to the extent that such Options would have been exercisable by the Participant on the date Participant's Service terminates and must be exercised by the Participant's legal representative, or authorized assignee, no later than twelve (12) months after the date Participant's Service terminates (or such shorter time period or longer time period as may be determined by the Committee), but in any event no later than the expiration date of the Options.
- (b) <u>Disability</u>. If the Participant's Service terminates because of the Participant's Disability, then the Participant's Options may be exercised only to the extent that such Options would have been exercisable by the Participant on the date Participant's Service terminates and must be exercised by the Participant (or the Participant's legal representative or authorized assignee) no later than twelve (12) months after the date Participant's Service terminates (or such shorter or longer time period as may be determined by the Committee, with any exercise beyond (a) three (3) months after the date Participant's Service terminates when the termination of Service is for a Disability that is not a "permanent and total disability" as defined in Section 22(e)(3) of the Code, or (b) twelve (12) months after the date Participant's Service terminates when the termination of Service is for a Disability that is a "permanent and total disability" as defined in Section 22(e)(3) of the Code, deemed to be exercise of an NSO), but in any event no later than the expiration date of the Options.
- (c) <u>Cause</u>. If the Participant is terminated for Cause, then Participant's Options shall expire on such Participant's date of termination of Service, or at such later time and on such conditions as are determined by the Committee, but in any no event later than the expiration date of the Options. Unless otherwise provided in the Award Agreement, Cause shall have the meaning set forth in the Plan.
- **5.7.** <u>Limitations on Exercise</u>. The Committee may specify a minimum number of Shares that may be purchased on any exercise of an Option, provided that such minimum number will not prevent any Participant from exercising the Option for the full number of Shares for which it is then exercisable.

- **5.8.** Limitations on ISOs. With respect to Awards granted as ISOs, to the extent that the aggregate Fair Market Value of the Shares with respect to which such ISOs are exercisable for the first time by the Participant during any calendar year (under all plans of the Company and any Parent or Subsidiary) exceeds one hundred thousand dollars (\$100,000), such Options will be treated as NSOs. For purposes of this Section 5.8, ISOs will be taken into account in the order in which they were granted. The Fair Market Value of the Shares will be determined as of the time the Option with respect to such Shares is granted. In the event that the Code or the regulations promulgated thereunder are amended after the Effective Date to provide for a different limit on the Fair Market Value of Shares permitted to be subject to ISOs, such different limit will be automatically incorporated herein and will apply to any Options granted after the effective date of such amendment.
- **5.9.** Modification, Extension or Renewal. The Committee may modify, extend or renew outstanding Options and authorize the grant of new Options in substitution therefor, provided that any such action may not, without the written consent of a Participant, impair any of such Participant's rights under any Option previously granted. Any outstanding ISO that is modified, extended, renewed or otherwise altered will be treated in accordance with Section 424(h) of the Code. Subject to Section 18 of this Plan, by written notice to affected Participants, the Committee may reduce the Exercise Price of outstanding Options without the consent of such Participants; provided, however, that the Exercise Price may not be reduced below the Fair Market Value on the date the action is taken to reduce the Exercise Price.
- **5.10.** No Disqualification. Notwithstanding any other provision in this Plan, no term of this Plan relating to ISOs will be interpreted, amended or altered, nor will any discretion or authority granted under this Plan be exercised, so as to disqualify this Plan under Section 422 of the Code or, without the consent of the Participant affected, to disqualify any ISO under Section 422 of the Code.
- **6. RESTRICTED STOCK AWARDS**. A Restricted Stock Award is an offer by the Company to sell to an eligible Employee, Consultant, or Director Shares that are subject to restrictions ("**Restricted Stock**"). The Committee will determine to whom an offer will be made, the number of Shares the Participant may purchase, the Purchase Price, the restrictions under which the Shares will be subject and all other terms and conditions of the Restricted Stock Award, subject to the Plan.
- **6.1.** Restricted Stock Purchase Agreement. All purchases under a Restricted Stock Award will be evidenced by an Award Agreement. Except as may otherwise be provided in an Award Agreement, a Participant accepts a Restricted Stock Award by signing and delivering to the Company an Award Agreement with full payment of the Purchase Price, within thirty (30) days from the date the Award Agreement was delivered to the Participant. If the Participant does not accept such Award within thirty (30) days, then the offer of such Restricted Stock Award will terminate, unless the Committee determines otherwise.
- **6.2.** <u>Purchase Price</u>. The Purchase Price for a Restricted Stock Award will be determined by the Committee and may be less than Fair Market Value on the date the Restricted Stock Award is granted. Payment of the Purchase Price must be made in accordance with Section 11 of the Plan, and the Award Agreement and in accordance with any procedures established by the Company.
- **6.3.** Terms of Restricted Stock Awards. Restricted Stock Awards will be subject to such restrictions as the Committee may impose or are required by law. These restrictions may be based on completion of a specified number of years of service with the Company or upon completion of Performance Factors, if any, during any Performance Period as set out in advance in the Participant's Award Agreement. Prior to the grant of a Restricted Stock Award, the Committee shall: (a) determine the nature, length and starting date of any Performance Period for the Restricted Stock Award; (b) select from among the Performance Factors to be used to measure performance goals, if any; and (c) determine the number of Shares that may be awarded to the Participant. Performance Periods may overlap and a Participant may participate simultaneously with respect to Restricted Stock Awards that are subject to different Performance Periods and having different performance goals and other criteria.
- **6.4.** <u>Termination of Service</u>. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee) and any Shares of Restricted Stock that are unvested as of such date shall be forfeited on such date for no consideration.
- **7. STOCK BONUS AWARDS**. A Stock Bonus Award is an award to an eligible Employee, Consultant, or Director of Shares for Services to be rendered or for past Services already rendered to the Company or any Parent or Subsidiary. All Stock Bonus Awards shall be made pursuant to an Award Agreement. No payment from the Participant will be required for Shares awarded pursuant to a Stock Bonus Award.
- **7.1.** <u>Terms of Stock Bonus Awards</u>. The Committee will determine the number of Shares to be awarded to the Participant under a Stock Bonus Award and any restrictions thereon. These restrictions may be based upon completion of a specified number of years of service with the Company or upon satisfaction of performance goals based on Performance Factors during any Performance Period as

set out in advance in the Participant's Stock Bonus Agreement. Prior to the grant of any Stock Bonus Award the Committee shall, as applicable:
(a) determine the nature, length and starting date of any Performance Period for the Stock Bonus Award; (b) select from among the Performance Factors to be used to measure performance goals; and (c) determine the number of Shares that may be awarded to the Participant. Performance Periods may overlap and a Participant may participate simultaneously with respect to Stock Bonus Awards that are subject to different Performance Periods and different performance goals and other criteria.

- **7.2.** <u>Form of Payment to Participant</u>. Payment may be made in the form of cash, whole Shares, or a combination thereof, based on the Fair Market Value of the Shares earned under a Stock Bonus Award on the date of payment, as determined in the sole discretion of the Committee.
- **7.3.** <u>Termination of Service</u>. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee) and any unvested portion of the Stock Bonus Award will be forfeited for no consideration on such date.
- **8.** <u>STOCK APPRECIATION RIGHTS</u>. A Stock Appreciation Right ("*SAR*") is an award to an eligible Employee, Consultant, or Director that may be settled in cash, or Shares (which may consist of Restricted Stock), having a value equal to (a) the difference between the Fair Market Value on the date of exercise over the Exercise Price multiplied by (b) the number of Shares with respect to which the SAR is being settled (subject to any maximum number of Shares that may be issuable as specified in an Award Agreement). All SARs shall be made pursuant to an Award Agreement.
- **8.1.** Terms of SARs. The Committee will determine the terms of each SAR including, without limitation: (a) the number of Shares subject to the SAR; (b) the Exercise Price and the time or times during which the SAR may be settled; (c) the consideration to be distributed on settlement of the SAR; and (d) the effect of the Participant's termination of Service on each SAR. The Exercise Price of the SAR will be determined by the Committee when the SAR is granted, and may not be less than Fair Market Value of the Shares on the date of grant. A SAR may be awarded upon satisfaction of Performance Factors, if any, during any Performance Period as are set out in advance in the Participant's individual Award Agreement. If the SAR is being earned upon the satisfaction of Performance Factors, then the Committee will: (x) determine the nature, length and starting date of any Performance Period for each SAR; and (y) select from among the Performance Factors to be used to measure the performance, if any. Performance Periods may overlap and Participants may participate simultaneously with respect to SARs that are subject to different Performance Factors and other criteria.
- **8.2.** Exercise Period and Expiration Date. A SAR will be exercisable within the times or upon the occurrence of events determined by the Committee and as set forth in the Award Agreement governing such SAR. The SAR Agreement shall set forth the expiration date; provided that no SAR will be exercisable after the expiration of ten (10) years from the date the SAR is granted. The Committee may also provide for SARs to become exercisable at one time or from time to time, periodically or otherwise (including, without limitation, upon the attainment during a Performance Period of performance goals based on Performance Factors), in such number of Shares or percentage of the Shares subject to the SAR as the Committee determines. Except as may be set forth in the Participant's Award Agreement, vesting ceases on the date Participant's Service terminates (unless determined otherwise by the Committee). Notwithstanding the foregoing, the rules of Section 5.6 also will apply to SARs.
- **8.3.** Form of Settlement. Upon exercise of a SAR, a Participant will be entitled to receive payment from the Company in an amount determined by multiplying (a) the difference between the Fair Market Value of a Share on the date of exercise over the Exercise Price; times (b) the number of Shares with respect to which the SAR is exercised. At the discretion of the Committee, the payment from the Company for the SAR exercise may be in cash, in Shares of equivalent value, or in some combination thereof. The portion of a SAR being settled may be paid currently or on a deferred basis with such interest or dividend equivalent, if any, as the Committee determines, provided that the terms of the SAR and any deferral satisfy the requirements of Section 409A of the Code.
- 8.4. <u>Termination of Service</u>. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee) and any SARs that remain unvested on such date shall be forfeited on such date for no consideration.
- **9. RESTRICTED STOCK UNITS**. A Restricted Stock Unit ("**RSU**") is an award to an eligible Employee, Consultant, or Director covering a number of Shares that may be settled in cash, or by issuance of those Shares (which may consist of Restricted Stock). All RSUs shall be made pursuant to an Award Agreement.

- **9.1.** Terms of RSUs. The Committee will determine the terms of an RSU including, without limitation: (a) the number of Shares subject to the RSU; (b) the time or times during which the RSU may be settled; (c) the consideration to be distributed on settlement; and (d) the effect of the Participant's termination of Service on each RSU. An RSU may be awarded upon satisfaction of such performance goals based on Performance Factors during any Performance Period as are set out in advance in the Participant's Award Agreement. If the RSU is being earned upon satisfaction of Performance Factors, then the Committee will: (x) determine the nature, length and starting date of any Performance Period for the RSU; (y) select from among the Performance Factors to be used to measure the performance, if any; and (z) determine the number of Shares deemed subject to the RSU. Performance Periods may overlap and participants may participate simultaneously with respect to RSUs that are subject to different Performance Periods and different performance goals and other criteria.
- **9.2.** Form and Timing of Settlement. Payment of earned RSUs shall be made as soon as practicable after the date(s) determined by the Committee and set forth in the Award Agreement. The Committee, in its sole discretion, may settle earned RSUs in cash, Shares, or a combination of both. The Committee may also permit a Participant to defer payment under a RSU to a date or dates after the RSU is earned provided that the terms of the RSU and any deferral satisfy the requirements of Section 409A of the Code.
- **9.3.** <u>Termination of Service</u>. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee).
- **10. PERFORMANCE AWARDS**. A "**Performance Award**" is an award to an eligible Employee, Consultant, or Director of a cash bonus or an award of Performance Shares denominated in Shares that may be settled in cash, or by issuance of those Shares (which may consist of Restricted Stock). Grants of Performance Awards shall be made pursuant to an Award Agreement.
- 10.1. Terms of Performance Awards. The Committee will determine, and each Award Agreement shall set forth, the terms of each Performance Award including, without limitation: (a) the amount of any cash bonus, (b) the number of Shares deemed subject to an award of Performance Shares; (c) the Performance Factors and Performance Period that shall determine the time and extent to which each Performance Award will be settled or paid (d) the consideration to be distributed on settlement or payment, and (e) the effect of the Participant's termination of Service on each Performance Award. In establishing Performance Factors and the Performance Period the Committee will: (x) determine the nature, length and starting date of any Performance Period; (y) select from among the Performance Factors to be used; and (z) determine the number of Shares deemed subject to the award of Performance Shares or the cash value of any cash bonus subject to a Performance Award. Prior to settlement the Committee shall determine the extent to which Performance Awards have been earned. Performance Periods may overlap and Participants may participate simultaneously with respect to Performance Awards that are subject to different Performance Periods and different performance goals and other criteria. No Participant will be eligible to receive more than \$5,000,000 in cash bonus Performance Awards in any annual Performance Period under this Plan and for any other Performance Period, such amount multiplied by a fraction, the numerator of which is the number of months in the Performance Period and the denominator of which is twelve (12).
- **10.2.** <u>Value, Earning and Timing of Performance Shares</u>. Each Performance Share will have an initial value equal to the Fair Market Value of a Share on the date of grant. After the applicable Performance Period has ended, the holder of Performance Shares will be entitled to receive a payout of the number of Performance Shares earned by the Participant over the Performance Period, to be determined as a function of the extent to which the corresponding Performance Factors or other vesting provisions have been achieved. The Committee, in its sole discretion, may pay earned Performance Shares in the form of cash, in Shares (which have an aggregate Fair Market Value equal to the value of the earned Performance Shares at the close of the applicable Performance Period) or in a combination thereof.
- **10.3.** <u>Termination of Service</u>. Except as may be set forth in the Participant's Award Agreement, vesting ceases on the date Participant's Service terminates (unless determined otherwise by the Committee) and any unvested Performance Awards shall be forfeited on such date for no consideration.
- 11. <u>PAYMENT FOR SHARE PURCHASES</u>. Payment from a Participant for Shares purchased pursuant to this Plan may be made in cash or by check or, where expressly approved for the Participant by the Committee and where permitted by law (and to the extent not otherwise set forth in the applicable Award Agreement):
  - (a) by cancellation of indebtedness of the Company to the Participant;
- (b) by surrender of shares of the Company held by the Participant that have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which said Award will be exercised or settled;
- (c) by waiver of compensation due or accrued to the Participant for services rendered or to be rendered to the Company or a Parent or Subsidiary of the Company;
- (d) by consideration received by the Company pursuant to a broker-assisted or other form of cashless exercise program implemented by the Company in connection with the Plan;

- (e) by any combination of the foregoing; or
- (f) by any other method of payment as is permitted by applicable law.
- 12. GRANTS TO NON-EMPLOYEE DIRECTORS. Non-Employee Directors are eligible to receive any type of Award offered under this Plan except ISOs. No Non-Employee Director may receive Awards under the Plan that, when combined with cash compensation received for service as a Non-Employee Director, exceed eight hundred thousand dollars (\$800,000) in value (as described below) in any calendar year. The value of Awards for purposes of complying with this maximum will be determined as follows: (a) for Options and SARs, grant date fair value will be calculated using the Company's regular valuation methodology for determining the grant date fair value of Options for reporting purposes and (b) for all other Awards other than Options and SARs, grant date fair value will be determined by either (i) calculating the product of the Fair Market Value per Share on the date of grant and the aggregate number of Shares subject to the Award, or (ii) calculating the product using an average of the Fair Market Value over a number of trading days and the aggregate number of Shares subject to the Award as determined by the Committee. Awards granted to an individual while he or she was serving in the capacity as an Employee or while he or she was a Consultant but not a Non-Employee Director will not count for purposes of the limitations set forth in this Section 12. Awards pursuant to this Section 12 may be automatically made pursuant to policy adopted by the Board, or made from time to time as determined in the discretion of the Board.
- **12.1.** <u>Eligibility.</u> Awards pursuant to this Section 12 shall be granted only to Non-Employee Directors. A Non-Employee Director who is elected or re-elected as a member of the Board will be eligible to receive an Award under this Section 12.
- **12.2.** <u>Vesting, Exercisability and Settlement</u>. Except as set forth in Section 21, Awards shall vest, become exercisable and be settled as determined by the Board. With respect to Options and SARs, the exercise price granted to Non-Employee Directors shall not be less than the Fair Market Value of the Shares at the time that such Option or SAR is granted.
- **12.3.** Election to receive Awards in Lieu of Cash. A Non-Employee Director may, if permitted by the Committee in its sole discretion, elect to receive his or her annual retainer payments and/or meeting fees from the Company in the form of cash or Awards or a combination thereof, as determined by the Committee. Such Awards shall be issued under the Plan. An election under this Section 12.3 shall be filed with the Company on the form prescribed by the Company.

#### 13. WITHHOLDING TAXES.

- 13.1. Withholding Generally. Whenever Shares are to be issued in satisfaction of Awards granted under this Plan or the applicable tax event occurs, the Company may require the Participant to remit to the Company, or to the Parent or Subsidiary employing the Participant, an amount sufficient to satisfy applicable U.S. federal, state, local and international withholding tax requirements or any other tax or social insurance liability legally due from the Participant prior to the delivery of Shares pursuant to exercise or settlement of any Award. Whenever payments in satisfaction of Awards granted under this Plan are to be made in cash, such payment will be net of an amount sufficient to satisfy applicable U.S. federal, state, local and international withholding tax or social insurance requirements or any other tax liability legally due from the Participant. The Fair Market Value of the Shares will be determined as of the date that the taxes are required to be withheld and such Shares will be valued based on the value of the actual trade or, if there is none, the Fair Market Value of the Shares as of the previous trading day.
- 13.2. Stock Withholding. The Committee, or its delegate(s), as permitted by applicable law, in its sole discretion and pursuant to such procedures as it may specify from time to time and to limitations of local law, may require or permit a Participant to satisfy such tax withholding obligation or any other tax liability legally due from the Participant, in whole or in part by (without limitation) (a) paying cash, (b) electing to have the Company withhold otherwise deliverable cash or Shares having a Fair Market Value equal to the minimum statutory amount required to be withheld, (c) delivering to the Company already-owned Shares having a Fair Market Value equal to the minimum amount required to be withheld or (d) withholding from the proceeds of the sale of otherwise deliverable Shares acquired pursuant to an Award either through a voluntary sale or through a mandatory sale arranged by the Company.

# 14. TRANSFERABILITY.

**14.1.** Transfer Generally. Unless determined otherwise by the Committee or pursuant to Section 14.2, an Award may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner other than by will or by the laws of descent or distribution. If the Committee makes an Award transferable, including, without limitation, by instrument to an inter vivos or testamentary trust in which the Awards are to be passed to beneficiaries upon the death of the trustor (settlor) or by gift or by domestic relations order to a Permitted Transferee, such Award will contain such additional terms and conditions as the Committee deems appropriate. All Awards shall be exercisable: (a) during the Participant's lifetime only by (i) the Participant, or (ii) the Participant's guardian or legal representative; (b) after the Participant's death, by the legal representative of the Participant's heirs or legatees; and (c) in the case of all awards except ISOs, by a Permitted Transferee.

14.2. Award Transfer Program. Notwithstanding any contrary provision of the Plan, the Committee shall have all discretion and authority to determine and implement the terms and conditions of any Award Transfer Program instituted pursuant to this Section 14.2 and shall have the authority to amend the terms of any Award participating, or otherwise eligible to participate in, any such Award Transfer Program, including (but not limited to) the authority to (a) amend (including to extend) the expiration date, post-termination exercise period and/or forfeiture conditions of any such Award, (b) amend or remove any provisions of the Award relating to the Award holder's continued service to the Company or its Parent or any Subsidiary, (c) amend the permissible payment methods with respect to the exercise or purchase of any such Award, (d) amend the adjustments to be implemented in the event of changes in the capitalization and other similar events with respect to such Award, and (e) make such other changes to the terms of such Award as the Committee deems necessary or appropriate in its sole discretion.

### 15. PRIVILEGES OF STOCK OWNERSHIP; RESTRICTIONS ON SHARES.

- **15.1.** <u>Voting and Dividends</u>. No Participant will have any of the rights of a stockholder with respect to any Shares until the Shares are issued to the Participant, except for any Dividend Equivalent Rights permitted by an applicable Award Agreement. Any Dividend Equivalent Rights shall be subject to the same vesting or performance conditions as the underlying Award. In addition, the Committee may provide that any Dividend Equivalent Rights permitted by an applicable Award Agreement shall be deemed to have been reinvested in additional Shares or otherwise reinvested. After Shares are issued to the Participant, the Participant will be a stockholder and have all the rights of a stockholder with respect to such Shares, including the right to vote and receive all dividends or other distributions made or paid with respect to such Shares; <u>provided</u>, that if such Shares are Restricted Stock, then any new, additional or different securities the Participant may become entitled to receive with respect to such Shares by virtue of a stock dividend, stock split or any other change in the corporate or capital structure of the Company will be subject to the same restrictions as the Restricted Stock; <u>provided</u>, <u>further</u>, that the Participant will have no right to retain such stock dividends or stock distributions with respect to Shares that are repurchased at the Participant's Purchase Price or Exercise Price, as the case may be, pursuant to Section 15.2.
- **15.2.** Restrictions on Shares. At the discretion of the Committee, the Company may reserve to itself and/or its assignee(s) a right to repurchase (a "*Right of Repurchase*") a portion of any or all Unvested Shares held by a Participant following such Participant's termination of Service at any time within ninety (90) days (or such longer or shorter time determined by the Committee) after the later of the date Participant's Service terminates and the date the Participant purchases Shares under this Plan, for cash and/or cancellation of purchase money indebtedness, at the Participant's Purchase Price or Exercise Price, as the case may be.
- **16.** <u>CERTIFICATES</u>. All Shares or other securities (whether or not certificated) delivered under this Plan will be subject to such stock transfer orders, legends and other restrictions as the Committee may deem necessary or advisable, including restrictions under any applicable U.S. federal, state or foreign securities law, or any rules, regulations and other requirements of the SEC or any stock exchange or automated quotation system upon which the Shares may be listed or quoted and any non-U.S. exchange controls or securities law restrictions to which the Shares are subject.
- 17. ESCROW; PLEDGE OF SHARES. To enforce any restrictions on a Participant's Shares, the Committee may require the Participant to deposit all certificates representing Shares, together with stock powers or other instruments of transfer approved by the Committee, appropriately endorsed in blank, with the Company or an agent designated by the Company to hold in escrow until such restrictions have lapsed or terminated, and the Committee may cause a legend or legends referencing such restrictions to be placed on the certificates. Any Participant who is permitted to execute a promissory note as partial or full consideration for the purchase of Shares under this Plan will be required to pledge and deposit with the Company all or part of the Shares so purchased as collateral to secure the payment of the Participant's obligation to the Company under the promissory note; provided, however, that the Committee may require or accept other or additional forms of collateral to secure the payment of such obligation and, in any event, the Company will have full recourse against the Participant under the promissory note notwithstanding any pledge of the Participant's Shares or other collateral. In connection with any pledge of the Shares, the Participant will be required to execute and deliver a written pledge agreement in such form as the Committee will from time to time approve. The Shares purchased with the promissory note may be released from the pledge on a pro rata basis as the promissory note is paid.
- **18. REPRICING**; **EXCHANGE AND BUYOUT OF AWARDS**. Without prior stockholder approval the Committee may (a) reprice Options or SARs (and where such repricing is a reduction in the Exercise Price of outstanding Options or SARs, the consent of the affected Participants is not required provided written notice is provided to them, notwithstanding any adverse tax consequences to them arising from the repricing), and (b) with the consent of the respective Participants (unless not required pursuant to Section 5.9 of the Plan), pay cash or issue new Awards in exchange for the surrender and cancellation of any, or all, outstanding Awards.

19. SECURITIES LAW AND OTHER REGULATORY COMPLIANCE. An Award will not be effective unless such Award is in compliance with all applicable U.S. and foreign federal and state securities and exchange control laws, rules and regulations of any governmental body, and the requirements of any stock exchange or automated quotation system upon which the Shares may then be listed or quoted, as they are in effect on the date of grant of the Award and also on the date of exercise or other issuance. Notwithstanding any other provision in this Plan, the Company will have no obligation to issue or deliver certificates for Shares under this Plan prior to: (a) obtaining any approvals from governmental agencies that the Company determines are necessary or advisable; and/or (b) completion of any registration or other qualification of such Shares under any state or federal or foreign law or ruling of any governmental body that the Company determines to be necessary or advisable. The Company will be under no obligation to register the Shares with the SEC or to effect compliance with the registration, qualification or listing requirements of any foreign or state securities laws, exchange control laws, stock exchange or automated quotation system, and the Company will have no liability for any inability or failure to do so.

**20. NO OBLIGATION TO EMPLOY.** Nothing in this Plan or any Award granted under this Plan will confer or be deemed to confer on any Participant any right to continue in the employ of, or to continue any other relationship with, the Company or any Parent, Subsidiary or Affiliate or limit in any way the right of the Company or any Parent, Subsidiary or Affiliate to terminate Participant's employment or other relationship at any time.

#### 21. CORPORATE TRANSACTIONS.

- 21.1. Assumption or Replacement of Awards by Successor. In the event of a Corporate Transaction any or all outstanding Awards may be assumed or replaced by the successor corporation, which assumption or replacement shall be binding on all Participants. In the alternative, the successor corporation may substitute equivalent Awards or provide substantially similar consideration to Participants as was provided to stockholders (after taking into account the existing provisions of the Awards). The successor corporation may also issue, in place of outstanding Shares of the Company held by the Participant, substantially similar shares, cash or other property subject to repurchase restrictions no less favorable to the Participant. In the event such successor or acquiring corporation (if any) refuses to assume, convert, replace or substitute Awards, as provided above, pursuant to a Corporate Transaction, then notwithstanding any other provision in this Plan to the contrary, such Awards shall have their vesting accelerate as to all shares subject to such Award (and any applicable rights of repurchase shall fully lapse) immediately prior to the Corporate Transaction. In addition, in the event such successor or acquiring corporation (if any) refuses to assume, convert, replace or substitute Awards, as provided above, pursuant to a Corporate Transaction, the Committee will (i) notify the Participant in writing or electronically that such Award will, if applicable, be exercisable for a period of time determined by the Committee in its sole discretion, and such Award will terminate upon the earlier of the expiration of such period or immediately prior to the Corporate Transaction or (ii) provide that each Award shall be cancelled immediately upon the occurrence of the Corporate Transaction in exchange for a payment in cash or securities in an amount equal to (A) the excess of the consideration paid per Share in the Corporate Transaction over the exercise price or purchase price (if any) per Share subject to the Award multipli
- 21.2. Assumption of Awards by the Company. The Company, from time to time, also may substitute or assume outstanding awards granted by another company, whether in connection with an acquisition of such other company or otherwise, by either; (a) granting an Award under this Plan in substitution of such other company's award; or (b) assuming such award as if it had been granted under this Plan if the terms of such assumed award could be applied to an Award granted under this Plan. Such substitution or assumption will be permissible if the holder of the substituted or assumed award would have been eligible to be granted an Award under this Plan if the other company had applied the rules of this Plan to such grant. In the event the Company assumes an award granted by another company, the terms and conditions of such award will remain unchanged (except that the Purchase Price or the Exercise Price, as the case may be, and the number and nature of Shares issuable upon exercise or settlement of any such Award will be adjusted appropriately pursuant to Section 424(a) of the Code). In the event the Company elects to grant a new Option in substitution of rather than assumption of an existing option, such new Option may be granted with a similarly adjusted Exercise Price. Substitute Awards shall not reduce the number of Shares authorized for grant under the Plan or authorized for grant to a Participant in a calendar year.
- **21.3.** Non-Employee Directors' Awards. Notwithstanding any provision to the contrary herein, in the event of a Corporate Transaction, the vesting of all Awards granted to Non-Employee Directors shall accelerate immediately prior to the consummation of such Corporate Transaction and such Awards shall become exercisable (as applicable) in full prior to the consummation of such event at such times and on such conditions as the Committee determines.

- **22. ADOPTION AND STOCKHOLDER APPROVAL**. This Plan shall be submitted for the approval of the Company's stockholders, consistent with applicable laws, within twelve (12) months before or after the date this Plan is adopted by the Board.
- **23. TERM OF PLAN/GOVERNING LAW**. Unless earlier terminated as provided herein, this Plan will become effective on the Effective Date and will terminate ten (10) years from the date this Plan is adopted by the Board. This Plan and all Awards granted hereunder shall be governed by and construed in accordance with the laws of the State of Delaware (excluding its conflict of law rules).
- **24.** <u>AMENDMENT OR TERMINATION OF PLAN</u>. The Board may at any time terminate or amend this Plan in any respect, including, without limitation, amendment of any form of Award Agreement or instrument to be executed pursuant to this Plan; <u>provided</u>, <u>however</u>, that the Board will not, without the approval of the stockholders of the Company, amend this Plan in any manner that requires such stockholder approval; <u>provided further</u>, that a Participant's Award shall be governed by the version of this Plan then in effect at the time such Award was granted.
- **25. NONEXCLUSIVITY OF THE PLAN**. Neither the adoption of this Plan by the Board, the submission of this Plan to the stockholders of the Company for approval, nor any provision of this Plan will be construed as creating any limitations on the power of the Board to adopt such additional compensation arrangements as it may deem desirable, including, without limitation, the granting of stock awards and bonuses otherwise than under this Plan, and such arrangements may be either generally applicable or applicable only in specific cases.
- **26. INSIDER TRADING POLICY**. Each Participant who receives an Award shall comply with any policy adopted by the Company from time to time covering transactions in the Company's securities by Employees, officers and/or directors of the Company.
- **27. ALL AWARDS SUBJECT TO COMPANY CLAWBACK OR RECOUPMENT POLICY**. All Awards, subject to applicable law, shall be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by the Board or required by law during the term of Participant's employment or other service with the Company that is applicable to executive officers, employees, directors or other service providers of the Company, and in addition to any other remedies available under such policy and applicable law, may require the cancellation of outstanding Awards and the recoupment of any gains realized with respect to Awards.
- 28. **DEFINITIONS**. As used in this Plan, and except as elsewhere defined herein, the following terms will have the following meanings:
- **28.1.** "Affiliate" means (i) any entity that, directly or indirectly, is controlled by, controls or is under common control with, the Company and (ii) any entity in which the Company has a significant equity interest, in either case as determined by the Committee, whether now or hereafter existing.
- **28.2.** "Amendment Effective Date" means the date on which the amendments to the Plan are approved by the Board and the Company stockholders.
- **28.3** "Award" means any award under the Plan, including any Option, Restricted Stock, Stock Bonus Award, Stock Appreciation Right, Restricted Stock Unit, Performance Award or award of Performance Shares.
- **28.4.** "Award Agreement" means, with respect to each Award, the written or electronic agreement between the Company and the Participant setting forth the terms and conditions of the Award, and country-specific appendix thereto for grants to non-U.S. Participants, which shall be in substantially a form (which need not be the same for each Participant) that the Committee (or in the case of Award agreements that are not used for Insiders, the Committee's delegate(s)) has from time to time approved, and will comply with and be subject to the terms and conditions of this Plan.
- **28.5.** "Award Transfer Program" means any program instituted by the Committee which would permit Participants the opportunity to transfer any outstanding Awards to a financial institution or other person or entity approved by the Committee.
  - **28.6.** "Board" means the Board of Directors of the Company.

- 28.7. "Cause" means (a) Participant's conviction (including a guilty plea or plea of nolo contendere) of any felony or any other crime involving fraud, dishonesty or moral turpitude; (b) Participant's commission or attempted commission of or participation in a fraud or act of dishonesty or misrepresentation against the Company that results (or could reasonably be expected to result) in material harm or injury to the business or reputation of the Company; (c) Participant's material violation of any contract or agreement between Participant and the Company, or of any Company policy, or of any statutory duty Participant owes to the Company; or (d) Participant's conduct that constitutes gross insubordination, incompetence or habitual neglect of duties and that results in (or could reasonably be expected to have resulted in) material harm to the business or reputation of the Company. The determination as to whether a Participant is being terminated for Cause shall be made in good faith by the Company and shall be final and binding on the Participant. The foregoing definition does not in any way limit the Company's ability to terminate a Participant's employment or consulting relationship at any time as provided in Section 20 above, and the term "Company" will be interpreted to include any Subsidiary or Parent, as appropriate. Notwithstanding the foregoing, the foregoing definition of "Cause" may, in part or in whole, be modified or replaced in each individual employment agreement or Award Agreement with any Participant, provided that such document supersedes the definition provided in this Section 28.6.
  - 28.8. "Code" means the United States Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.
- **28.9.** "Committee" means the Compensation Committee of the Board or those persons to whom administration of the Plan, or part of the Plan, has been delegated as permitted by law.
  - **28.10.** "Common Stock" means the common stock of the Company.
  - 28.11. "Company" means Sierra Oncology, Inc., or any successor corporation.
- **28.12.** "Consultant" means any natural person, including an advisor or independent contractor, engaged by the Company or a Parent, Subsidiary or Affiliate to render services to such entity.
- 28.13. "Corporate Transaction" means the occurrence of any of the following events: (a) any "Person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "beneficial owner" (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the total voting power represented by the Company's then-outstanding voting securities; provided, however, that for purposes of this subclause (a) the acquisition of additional securities by any one Person who is considered to own more than fifty percent (50%) of the total voting power of the securities of the Company will not be considered a Corporate Transaction; (b) the consummation of the sale or disposition by the Company of all or substantially all of the Company's assets; (c) the consummation of a merger or consolidation of the Company with any other corporation, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) at least fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation; (d) any other transaction which qualifies as a "corporate transaction" under Section 424(a) of the Code wherein the stockholders of the Company give up all of their equity interest in the Company (except for the acquisition, sale or transfer of all or substantially all of the outstanding shares of the Company) or (e) a change in the effective control of the Company that occurs on the date that a majority of members of the Board are replaced during any twelve (12) month period by members of the Board whose appointment or election is not endorsed by as majority of the members of the Board prior to the date of such appointment or election. For purpose of this subclause (e), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Corporate Transaction. For purposes of this definition, Persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company. Notwithstanding the foregoing, to the extent that any amount constituting deferred compensation (as defined in Section 409A of the Code) would become payable under this Plan by reason of a Corporate Transaction, such amount shall become payable only if the event constituting a Corporate Transaction would also qualify as a change in ownership or effective control of the Company or a change in the ownership of a substantial portion of the assets of the Company, each as defined within the meaning of Code Section 409A, as it has been and may be amended from time to time, and any proposed or final Treasury Regulations and IRS guidance that has been promulgated or may be promulgated thereunder from time to time.
  - **28.14.** "*Director*" means a member of the Board.
- **28.15.** "*Disability*" means in the case of incentive stock options, total and permanent disability as defined in Section 22(e)(3) of the Code and in the case of other Awards, that the Participant is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than 12 months.

- **28.16.** "*Dividend Equivalent Right*" means the right of a Participant, granted at the discretion of the Committee or as otherwise provided by the Plan or an Award Agreement, to receive a credit for the account of such Participant in an amount equal to the cash, stock or other property dividends in amounts equal equivalent to cash, stock or other property dividends for each Share represented by an Award held by such Participant.
- **28.17.** "Effective Date" means the day immediately prior to the date of the underwritten initial public offering of the Company's Common Stock pursuant to a registration statement that is declared effective by the SEC.
- **28.18.** "*Employee*" means any person, including Officers and Directors, providing services as an employee to the Company or any Parent, Subsidiary or Affiliate. Neither service as a Director nor payment of a director's fee by the Company will be sufficient to constitute "employment" by the Company.
  - 28.19. "Exchange Act" means the United States Securities Exchange Act of 1934, as amended.
- **28.20.** "Exchange Program" means a program pursuant to which (a) outstanding Awards are surrendered, cancelled or exchanged for cash, the same type of Award or a different Award (or combination thereof) or (b) the exercise price of an outstanding Award is increased or reduced.
- **28.21.** "Exercise Price" means, with respect to an Option, the price at which a holder may purchase the Shares issuable upon exercise of an Option and with respect to a SAR, the price at which the SAR is granted to the holder thereof.
  - 28.22. "Fair Market Value" means, as of any date, the value of a share of the Company's Common Stock determined as follows:
- (a) if such Common Stock is publicly traded and is then listed on a national securities exchange, its closing price on the date of determination on the principal national securities exchange on which the Common Stock is listed or admitted to trading as reported in *The Wall Street* Journal or such other source as the Committee deems reliable;
- (b) if such Common Stock is publicly traded but is neither listed nor admitted to trading on a national securities exchange, the average of the closing bid and asked prices on the date of determination as reported in *The Wall Street Journal* or such other source as the Committee deems reliable;
- (c) in the case of an Option or SAR grant made on the Effective Date, the price per share at which shares of the Company's Common Stock are initially offered for sale to the public by the Company's underwriters in the initial public offering of the Company's Common Stock pursuant to a registration statement filed with the SEC under the Securities Act; or
  - (d) if none of the foregoing is applicable, by the Board or the Committee in good faith.
- **28.23.** "*Insider*" means an officer or director of the Company or any other person whose transactions in the Company's Common Stock are subject to Section 16 of the Exchange Act.
  - 28.24. "IRS" means the United States Internal Revenue Service.
  - **28.25.** "Non-Employee Director" means a Director who is not an Employee of the Company or any Parent or Subsidiary.
  - **28.26.** "Option" means an award of an option to purchase Shares pursuant to Section 5.
- **28.27.** "*Parent*" means any corporation (other than the Company) in an unbroken chain of corporations ending with the Company if each of such corporations other than the Company owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.
  - 28.28. "Participant" means a person who holds an Award under this Plan.
  - **28.29.** "Performance Award" means cash or stock granted pursuant to Section 10 of the Plan.

<b>28.30.</b> "Performance Factors" means any of the factors selected by the Committee and specified in an Award Agreement, from among the
following objective measures, either individually, alternatively or in any combination, applied to the Company as a whole or any business unit or
Subsidiary, either individually, alternatively, or in any combination, on a GAAP or non-GAAP basis, and measured, to the extent applicable on an
absolute basis or relative to a pre-established target, to determine whether the performance goals established by the Committee with respect to applicable
Awards have been satisfied:

- (a) Profit Before Tax;
- (b) Billings;
- (c) Revenue;
- (d) Net revenue;
- (e) Earnings (which may include earnings before interest and taxes, earnings before taxes, and net earnings);
- (f) Operating income;
- (g) Operating margin;
- (h) Operating profit;
- (i) Controllable operating profit, or net operating profit;
- (j) Net Profit;
- (k) Gross margin;
- (l) Operating expenses or operating expenses as a percentage of revenue;
- (m) Net income;
- (n) Earnings per share;
- (o) Total stockholder return;
- (p) Market share;
- (q) Return on assets or net assets;
- (r) The Company's stock price;
- (s) Growth in stockholder value relative to a pre-determined index;
- (t) Return on equity;
- (u) Return on invested capital;
- (v) Cash Flow (including free cash flow or operating cash flows)
- (w) Cash conversion cycle;
- (x) Economic value added;
- (y) Individual confidential business objectives;
- (z) Contract awards or backlog;
- (aa) Overhead or other expense reduction;
- (bb) Credit rating;
- (cc) Strategic plan development and implementation;
- (dd) Succession plan development and implementation;
- (ee) Improvement in workforce diversity;
- (ff) Customer indicators;
- (gg) New product invention or innovation;
- (hh) Attainment of research and development milestones;

- (ii) Improvements in productivity;
- (jj) Bookings; and
- (kk) Attainment of objective operating goals and employee metrics.

The Committee may, in recognition of unusual or non-recurring items such as acquisition-related activities or changes in applicable accounting rules, provide for one or more equitable adjustments (based on objective standards) to the Performance Factors to preserve the Committee's original intent regarding the Performance Factors at the time of the initial award grant. It is within the sole discretion of the Committee to make or not make any such equitable adjustments.

- **28.31.** "*Performance Period*" means the period of service determined by the Committee, not to exceed five (5) years, during which years of service or performance is to be measured for the Award.
  - **28.32.** "*Performance Share*" means an Award granted pursuant to Section 10 of the Plan.
- **28.33.** "*Permitted Transferee*" means any child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law (including adoptive relationships) of the Employee, any person sharing the Employee's household (other than a tenant or employee), a trust in which these persons (or the Employee) have more than 50% of the beneficial interest, a foundation in which these persons (or the Employee) control the management of assets, and any other entity in which these persons (or the Employee) own more than 50% of the voting interests.
- 28.34. "Plan" means this Sierra Oncology, Inc. 2015 Equity Incentive Plan (formerly called the ProNai Therapeutics, Inc. 2015 Equity Incentive Plan).
- **28.35.** "*Purchase Price*" means the price to be paid for Shares acquired under the Plan, other than Shares acquired upon exercise of an Option or SAR.
  - 28.36. "Restricted Stock Award" means an award of Shares pursuant to Section 6 of the Plan, or issued pursuant to the early exercise of an Option.
  - **28.37.** "Restricted Stock Unit" means an Award granted pursuant to Section 9 of the Plan.
  - 28.38. "SEC" means the United States Securities and Exchange Commission.
  - **28.39.** "Securities Act" means the United States Securities Act of 1933, as amended.
- 28.40. "Service" shall mean service as an Employee, Consultant, Director or Non-Employee Director, to the Company or a Parent, Subsidiary or Affiliate, subject to such further limitations as may be set forth in the Plan or the applicable Award Agreement. An Employee will not be deemed to have ceased to provide Service in the case of (a) sick leave, (b) military leave, or (c) any other leave of absence approved by the Company; provided, that such leave is for a period of not more than 90 days (x) unless reemployment upon the expiration of such leave is guaranteed by contract or statute, or (y) unless provided otherwise pursuant to formal policy adopted from time to time by the Company and issued and promulgated to employees in writing. In the case of any Employee on an approved leave of absence or a reduction in hours worked (for illustrative purposes only, a change in schedule from that of full-time to part-time), the Committee may make such provisions regarding suspension of or modification of vesting of the Award while on leave from the employ of the Company or a Parent, Subsidiary or Affiliate or during such change in working hours as it may deem appropriate, except that in no event may an Award be exercised after the expiration of the term set forth in the applicable Award Agreement. In the event of military leave, if required by applicable laws, vesting shall continue for the longest period that vesting continues under any other statutory or Company approved leave of absence and, upon a Participant's returning from military leave (under conditions that would entitle him or her to protection upon such return under the Uniform Services Employment and Reemployment Rights Act), he or she shall be given vesting credit with respect to Awards to the same extent as would have applied had the Participant continued to provide services to the Company throughout the leave on the same terms as he or she was providing services immediately prior to such leave. Except as set forth in this Section 28.39, an employee shall have terminated employment as of the date he or she ceases provide services (regardless of whether the termination is in breach of local employment laws or is later found to be invalid) and employment shall not be extended by any notice period or garden leave mandated by local law, provided however, that a change in status from an employee to a consultant or advisor shall not terminate the service provider's Service, unless determined by the Committee, in its discretion. The Committee will have sole discretion to determine whether a Participant has ceased to provide Services and the effective date on which the Participant ceased to provide Services.

- 28.41. "Shares" means shares of Common Stock and the common stock of any successor entity.
- 28.42. "Stock Appreciation Right" means an Award granted pursuant to Section 8 of the Plan.
- 28.43. "Stock Bonus" means an Award granted pursuant to Section 7 of the Plan.
- **28.44.** "*Subsidiary*" means any corporation (other than the Company) in an unbroken chain of corporations beginning with the Company if each of the corporations other than the last corporation in the unbroken chain owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.
  - 28.45. "Treasury Regulations" means regulations promulgated by the United States Treasury Department.
- **28.46.** "*Unvested Shares*" means Shares that have not yet vested or are subject to a right of repurchase in favor of the Company (or any successor thereto).

#### SIERRA ONCOLOGY, INC.

(the "Company")

#### 2015 EQUITY INCENTIVE PLAN

(the "Plan")

#### ADDENDUM FOR CANADIAN PARTICIPANTS

- A. The Company has adopted the Plan, to be effective on the Effective Date.
- B. The Company desires to modify certain terms of the Plan in their application for Directors, Non-Employee Directors and Employees (as those terms are defined in the Plan) who are resident in Canada for purposes of the *Income Tax Act* (Canada) or otherwise subject to Canadian personal income tax (the "Canadian Participants").
- C. Under the Income Tax Act (Canada), Directors, Non-Employee Directors and Employees who are Canadian Participants are treated as officers and employees for purposes of that Act.

**NOW THEREFORE**, the Company does hereby amend certain terms and conditions of the Plan as they apply to the Canadian Participants, as follows.

- 1. <u>Defined Terms</u>. In this Addendum, all defined terms shall have the respective meanings set forth in the Plan, unless otherwise defined herein.
- 2. <u>Effective Date</u>. The effective date of this Addendum is the Effective Date.

### 3. Options.

- (a) Options granted to Canadian Participants will be NSOs.
- (b) Notwithstanding section 5.2 of the Plan, the grant date of an Option awarded to a Canadian Participant shall be, in all cases, the date the Option is actually granted to the Canadian Participant, as evidenced by the Award Agreement.
- (c) Notwithstanding section 5.1 of the Plan, satisfaction of Performance Factors, if any, will be treated as a condition subsequent to the grant to a Canadian Participant of an Option giving rise to a risk of forfeiture of the Option and not a condition precedent to the grant of the Option.
- (d) For purposes of section 5.9 of the Plan, Options granted to a Canadian Participant will not be modified or altered, or new options granted in substitution therefor, if such modification, alteration or substitution has a material adverse affect on such Canadian Participant's tax treatment of such Options, except with such Canadian Participant's consent.

#### 4. Stock Bonus Awards.

Section 7.2 of the Plan shall be modified as it applies to Canadian Participants such that the Company is required to issue Shares in payment of a Stock Bonus Award to a Canadian Participant and the Company cannot choose, at its option, to make such payment in cash or a combination of cash and Shares, and section 7.2 shall read as follows:

"7.2. Form of Payment to Canadian Participant. Payment of a Stock Bonus Award to a Canadian Participant shall be settled solely by the issuance of Shares."

#### 5. Stock Appreciation Rights.

- (a) Section 8.2 of the Plan shall be modified as it applies to Canadian Participants such that the Committee will provide that a SAR (or a portion thereof) becomes exercisable on the date of vesting of the SAR (or portion thereof), which date will be the date of exercise of the SAR (or portion thereof) for purposes of section 8.3 of the Plan. The relevant SAR (or portion thereof) will be deemed to be exercised on that date and the Canadian Participant will be immediately entitled to receive payment from the Company under section 8.3 of the Plan.
- (b) Section 8.3 of the Plan shall be modified as it applies to Canadian Participants such that each SAR (or portion thereof) that vests and is deemed to be exercised pursuant to section 8.2 of the Plan (as modified by section 4(a) of this Addendum) shall be settled and paid out to the Canadian Participant as soon as practicable after the date of such vesting, and the terms of the SAR shall not, in any circumstances, provide for a deferral of such payment.

### 6. Restricted Stock Units.

Section 9.2 of the Plan shall be modified as it applies to Canadian Participants such that the Company agrees to issue only Shares in payment of RSUs to a Canadian Participant and the Company cannot choose, at its option, to make such payment in cash or a combination of cash and Shares, and section 9.2 shall read as follows:

"9.2. <u>Form and Timing of Settlement to Canadian Participants</u>. Payment of earned RSUs of a Canadian Participant shall be made as soon as practicable after the date(s) determined by the Committee and set forth in the Award Agreement. Such earned RSUs shall be settled solely by the issuance of Shares. The Committee may permit a Canadian Participant to defer settlement and the issuance of Shares in payment of an earned RSU to a date that is acceptable to the Committee, provided that the terms of the Award Agreement, the RSUs and any deferral meet the conditions of section 7 of the *Income Tax Act* (Canada)."

#### 7. Performance Awards.

- (a) Section 10.1 of the Plan shall be modified as it applies to Canadian Participants and shall read as follows:
  - "10.1 Terms of Performance Awards. The Committee will determine, and each Award Agreement shall set for the terms of each Performance Award, including, without limitation, the consideration to be distributed on settlement or payment; the Performance Factors and the Performance Period that shall determine the time and extent to which each Performance Award will be settled or paid; and the effect of the Canadian Participant's termination of Service on each Performance Award. In establishing Performance Factors and the Performance Period the Committee will: (x) determine the nature, length and starting date of any Performance Period; (y) select from among the Performance Factors to be used; and (z) determine the number of Shares deemed subject to the award of Performance Shares or the cash value of any cash bonus subject to a Performance Award.
  - 10.1.1 If the Performance Award is in the form of a cash bonus, the Committee shall determine, and the Award Agreement shall provide, that the Performance Award must be paid out to the Canadian Participant within three (3) years after the end of the first year in which the services were performed and in respect of which that Performance Award is granted.
  - 10.1.2 If the Performance Award is in the form of Performance Shares, the Committee shall determine, and the Award Agreement shall set forth, the number of Shares deemed subject to such award of Performance Shares.
  - 10.1.3 Prior to settlement of any Performance Award the Committee shall determine the extent to which such Performance Award has been earned. Subject to section 10.1.1, Performance Periods may overlap and Participants may participate simultaneously with respect to Performance Awards that are, subject to different Performance Periods and different performance goals and other criteria. No Participant will be eligible to receive more than \$5,000,000 in cash bonus Performance Awards in any annual Performance Period under this Plan, and for any other Performance Period, such amount multiplied by a fraction, the number of which is the number of months in the Performance period and the denominator of which is twelve (12)."
- (b) Section 10.2 of the Plan shall be modified as it applies to Canadian Participants in respect of Performance Shares such that the Company agrees to issue only Shares in payment of awards of Performance Shares to a Canadian Participant and neither the Committee nor the Company may choose, at its option, to make such payment in cash or a combination of cash and Shares.

#### 8. Payment for Share Purchases.

Section 11(b) of the Plan shall be modified as at applies to Canadian Participants with respect to the consideration that may be paid by Canadian Participants for Shares purchased pursuant to the Plan. In no circumstances shall a Canadian Participant be permitted to make, and the Committee shall not approve, a payment by the Canadian Participant by the surrender of any Shares that were acquired at any time by the Canadian Participant on the exercise of any Option.

#### 9. Withholding Taxes.

(a) Section 13.1 of the Plan shall be modified as it applies to Canadian Participants and shall read as follows:

"13.1 Withholding for Canadian Participants." The Company or any Affiliate may take such reasonable steps for the deduction and withholding of any taxes and other required source deductions which the Company or Affiliate, as the case may be, is required by law or regulation of any governmental authority whatsoever to remit in connection with the exercise or settlement of any Award granted to a Canadian Participant. Without limiting the generality of the foregoing, whenever a settlement or payment is made by the issuance of Shares to a Canadian Participant in satisfaction of Awards granted under this Plan, the Company or Affiliate, as the case may be, may, at its discretion (i) deduct and withhold those amounts it is required to remit from any cash remuneration or other amount payable to the Canadian Participant, whether or not such amount payable is related to the Plan, or the exercise or settlement of any Awards; (ii) permit the Canadian Participant to make a cash payment to the Company or Affiliate, as the case may be, equal to the amount required to be remitted; or (iii) sell, on behalf of the Canadian Participant, that number of Shares to be issued on the exercise or settlement such that the amount of the proceeds of such sale will be sufficient to satisfy any taxes or other source deductions required to be remitted for the account of the Canadian Participant. If the Company or Affiliate, as the case may be,

considers that the foregoing steps undertaken in connection with this section 13.1 result in inadequate withholding or a late remittance of taxes or other source deductions, then the delivery of Shares to be issued on the exercise or settlement of Awards may be made conditional upon the Canadian Participant (or other person) reimbursing or compensating the Company or Affiliate or making arrangements satisfactory to the Company or Affiliate for the payment in a timely manner of all taxes and other source deductions required to be remitted."

(b) Section 13.2 of the Plan shall not apply to Canadian Participants. For greater certainty, the Committee shall not approve funding by a Canadian Participant of withholding taxes or other source deductions by the withholding of Shares the Canadian Participant is otherwise entitled to receive or the surrender by the Canadian Participant of any Shares that were acquired at any time by the Canadian Participant on the exercise of any Option.

# LIST OF SUBSIDIARIES OF SIERRA ONCOLOGY, INC.

Subsidiary	Jurisdiction of Incorporation or Organization
Sierra Oncology Canada ULC	Canada, British Columbia

# CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-205693, 333-209897, 333-216392, 333-223253, 333-228263, and 333-229933 on Form S-8, and Registration Statement Nos. 333-225650 and 333-234554 on Form S-3 of our report dated March 3, 2020, relating to the consolidated financial statements of Sierra Oncology, Inc. and subsidiaries (the "Company") appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2019.

/s/ Deloitte & Touche LLP

Grand Rapids, Michigan March 3, 2020

### CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

- I, Nick Glover, certify that:
- 1. I have reviewed this Annual Report on Form 10-K of Sierra Oncology, 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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- 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 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 3, 2020

/s/ Nick Glover

Dr. Nick Glover Chief Executive Officer (Principal Executive Officer)

### CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

- I, Sukhi Jagpal, certify that:
- 1. I have reviewed this Annual Report on Form 10-K of Sierra Oncology, 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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles:
- 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 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 3, 2020

/s/ Sukhi Jagpal
Sukhi Jagpal
Chief Financial Officer
(Principal Financial Officer)

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Nick Glover, Chief Executive Officer of Sierra Oncology, Inc. (Company), do 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 my knowledge:

- the Annual Report on Form 10-K of the Company for the year ended December 31, 2019 (Report), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: March 3, 2020

/s/ Nick Glover

Dr. Nick Glover
Chief Executive Officer
(Principal Executive Officer)

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Sukhi Jagpal, Chief Financial Officer of Sierra Oncology, Inc. (Company), do 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 my knowledge:

- the Annual Report on Form 10-K of the Company for the year ended December 31, 2019 (Report), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: March 3, 2020

/s/ Sukhi Jagpal
Sukhi Jagpal
Chief Financial Officer
(Principal Financial Officer)