Filed Pursuant to Rule 424(b)(4)
Registration No. 333-249748

Prospectus

11,000,000 shares

Common stock

This is an initial public offering of shares of common stock by Olema Pharmaceuticals, Inc. We are offering 11,000,000 shares of our common stock to be sold in the offering. The initial public offering price is $19.00 per share.

Prior to this offering, there has been no public market for our common stock. Our common stock has been approved for listing on The Nasdaq Global Select Market under the symbol “OLMA.”

We are an “emerging growth company” as defined under the federal securities laws and, as such, have elected to comply with certain reduced reporting requirements.

	Per share	Total
Initial public offering price	$ 19.00	$209,000,000.00
Underwriting discounts and commissions(1)	$ 1.33	$ 14,630,000.00
Proceeds to Olema Pharmaceuticals, Inc., before expenses	$ 17.67	$194,370,000.00

(1) See the section titled “Underwriting” beginning on page 183 for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to 1,650,000 additional shares of common stock at the initial public offering price, less the underwriting discounts and commissions.

Investing in our common stock involves a high degree of risk. See the section titled “Risk Factors” beginning on page 11.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on or about November 23, 2020.

J.P. Morgan Jefferies Cowen Canaccord Genuity

November 18, 2020

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Through and including December 13, 2020 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Neither we nor the underwriters have authorized anyone to provide you any information or make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

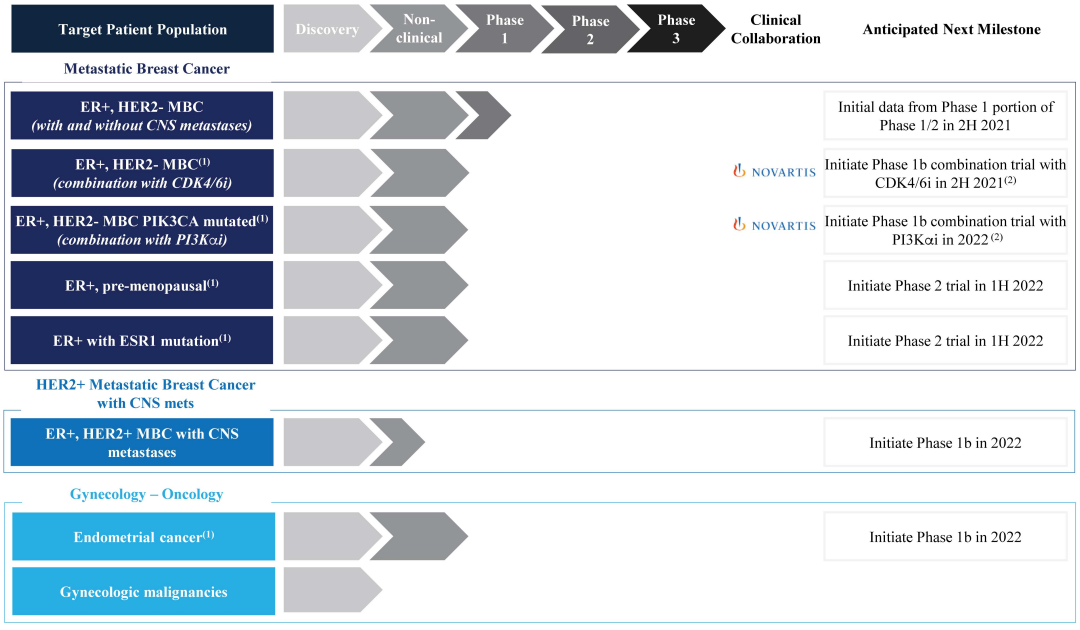
For investors outside of the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

Prospectus summary

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including the sections in this prospectus titled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Unless otherwise indicated, all references in this prospectus to "Olema," the "company," "we," "our," "us" or similar terms refer to Olema Pharmaceuticals, Inc.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of next generation targeted therapies for women's cancers. Our team has spent the past decade characterizing the structure and function of the estrogen receptor, or ER, a key driver of breast cancer in approximately 75% of patients, in order to develop more potent, oral therapies that completely inactivate this signaling pathway. Our lead product candidate, OP-1250, is a novel oral therapy with combined activity as both a complete ER antagonist, or CERAN, and a selective ER degrader, or SERD, which we believe will drive deeper, more durable responses than existing therapies. OP-1250, both as a monotherapy and in combination with inhibitors of cyclin-dependent kinase 4 and 6, or CDK4/6, demonstrated robust tumor shrinkage in several xenograft models, including a breast cancer brain metastasis model. In August 2020, we initiated an ongoing Phase 1/2 dose escalation and expansion trial evaluating OP-1250 for the treatment of recurrent, locally advanced or metastatic ER-positive, or ER+, human epidermal growth factor receptor 2-negative, or HER2-, breast cancer, and expect to report initial data from this trial in the second half of 2021. We own worldwide development and commercialization rights to OP-1250. As summarized in the figure below, our plan is to develop OP-1250 in a number of ER+ breast cancer indications, both as a monotherapy and in combination with approved targeted therapies that have shown improved outcomes with other endocrine therapies. We believe OP-1250's oral formulation and dual mechanism of action directly address the limitations of current endocrine therapies, such as fulvestrant and tamoxifen, and position OP-1250 as a potential endocrine therapy of choice for the treatment of ER+ breast cancers. Our goal is to transform the standard of care for women living with cancers by developing more effective therapies that apply our deep understanding and collective expertise in endocrine-driven cancers, nuclear receptor activities and mechanisms of acquired resistance.



MBC = metastatic breast cancer; PI3Kα = phosphatidylinositol 3-kinase alpha; RP2D = recommended Phase 2 dose. CDK4/6i = CDK4/6 inhibitor; PI3Kαi = PI3Kα inhibitor

(1) *Patient population may be studied as additional cohort(s) of current Phase 1/2 clinical trial or may be studied in a separate clinical trial.*
(2) *Anticipated initiation of Phase 1b is after determination of RP2D of current Phase 1/2 trial.*

We are initially focused on developing therapies for the treatment of breast cancer, which represents approximately 30% of all new diagnoses of women's cancer. In 2020, the American Cancer Society, or ACS, estimates there will be approximately 276,000 new cases of female breast cancer and over 42,000 deaths from metastatic breast cancer in the United States. Treatment decisions are based on a combination of individual patient characteristics and tumor biology, most importantly the expression of three proteins: ER, progesterone receptor, or PR, and human epidermal growth factor receptor 2, or HER2. Approximately 75% of all breast cancers are ER+, and approximately 65% are ER+/HER2-, highlighting the central role of the ER in driving a large majority of breast cancer. Approximately 6-10% of breast cancer patients present with metastatic disease at diagnosis and a further 20-30% of patients initially diagnosed with early-stage disease ultimately develop metastatic disease. The current five-year survival rate for patients with ER+ metastatic breast cancer is approximately 30%. In 2019, worldwide sales for endocrine and targeted therapies treating ER+ breast cancer patients totaled $9.6 billion.

The ER is a nuclear receptor that functions as a ligand regulated transcription factor. When bound to estrogen, the ER directs the expression of genes that are essential for breast cancer cells' survival and proliferation. For more than four decades, researchers have been developing new approaches and therapies to prevent activation of the ER pathway, thereby inhibiting the ability of the ER to drive tumor cell growth. In 1977, the first endocrine therapeutic, the anti-estrogen tamoxifen, was approved by the U.S. Food and Drug Administration, or FDA, for the treatment of breast cancer. Tamoxifen is still commonly used today but is challenged by the development of acquired drug resistance, which in some cases may be due to its partial agonist activity. In search for a different mechanism to target the estrogen pathway, aromatase inhibitors, or AIs, were developed in the 1990s to block the synthesis of estrogen and deprive ER+ cells of its activating ligand. However, up to 50% of patients taking AIs develop arthralgia, leading to suspension of treatment in up to 15% of patients. Additionally, most patients with metastatic breast cancer have been shown to ultimately develop resistance to AIs. These agents are also not used to treat pre-menopausal women without the addition of ovarian suppression.

In 2002, fulvestrant was approved as a treatment for hormone receptor positive, or HR+, metastatic breast cancer patients and is typically used as a second- or third-line endocrine agent. Fulvestrant was designed to be a CERAN, and later discovered to also be a SERD, and represented a breakthrough for the field with improved outcomes for patients whose disease had progressed on prior endocrine therapy. However, fulvestrant has several limitations including its suboptimal drug exposure and route of administration as a monthly intramuscular injection. Despite these drawbacks, fulvestrant achieved worldwide sales of over $1.1 billion in 2019.

More recently, the field has focused on the discovery and development of oral agents that have fulvestrant's dual mechanism of action to completely inactivate and degrade the ER. Some of these oral SERD agents are CERANs, such as OP-1250, but others have partial agonist activity despite being SERDs and thus are not CERANs. SERDs reduce the levels of the ER but they do not entirely eliminate it. Consequently, SERDs are not necessarily CERANs. Notably, estrogen itself leads to ER degradation.

Our product candidate

We designed our wholly-owned, lead product candidate, OP-1250, based both on a detailed structural understanding of the ER and on known alterations to this structure induced by fulvestrant and other ligands. We have demonstrated in nonclinical studies that OP-1250 functions both as a CERAN and a SERD, but is distinguished from fulvestrant in several noteworthy ways, including:

- *OP-1250 is orally bioavailable while fulvestrant is a highly insoluble compound that must be administered monthly by intramuscular injection into the buttocks;*
- *OP-1250 has favorable biodistribution properties leading to higher drug concentrations in the plasma and tumor than those achieved with fulvestrant, as shown in a head-to-head mouse xenograft study; and*
- *OP-1250 has demonstrated the ability to shrink tumors in head-to-head nonclinical studies with fulvestrant, in contrast to fulvestrant, which has only been shown to inhibit tumor growth.*

Based on these nonclinical differences, we believe that OP-1250 has the potential to demonstrate clinical outcomes superior to fulvestrant. Furthermore, OP-1250 has the potential to benefit patients with metastatic

breast cancer, initially for patients who have previously received endocrine therapy, as well as those who are treatment naïve in the metastatic setting, and advance into the adjuvant setting for early-stage ER+ breast cancer. In multiple nonclinical animal models of anti-cancer activity, including patient-derived xenografts with tumors containing activating mutations in the ER, OP-1250 monotherapy led to tumor shrinkage or in some cases tumor eradication, as well as long-term post-treatment survival. In each of these nonclinical models, the effect of OP-1250 was superior to that of fulvestrant, an effect which we determined was driven both by improved pharmacokinetic, or PK, properties and higher plasma and tumor drug concentrations. In nonclinical studies, OP-1250 demonstrated robust central nervous system, or CNS, penetration, and in an intracranial breast cancer brain metastases xenograft study, OP-1250 demonstrated the ability to shrink tumors and improve survival in mice. OP-1250 has the potential to address a critical unmet need as 10-15% of ER+ breast cancer patients develop brain metastases for which there are currently limited treatment options.

In August 2020, we initiated a Phase 1/2 clinical trial of OP-1250 in patients with recurrent, locally advanced or metastatic ER+/HER2- breast cancer whose disease has progressed on endocrine therapy. Phase 1 consists of monotherapy dose escalation to evaluate the safety and PK of OP-1250 and to determine the maximum tolerated dose, or MTD, and/or the recommended Phase 2 dose, or RP2D. The expansion phase will enroll patients at the RP2D in order to explore preliminary efficacy in selected patient populations. The first cohort of the expansion phase will consist of women and men with recurrent, locally advanced or metastatic breast cancer whose disease has progressed on prior endocrine therapy. A second cohort is exploratory and will enroll individuals with metastatic breast cancer who have brain metastases. As of October 23, 2020, the first dose cohort, consisting of four patients, has completed enrollment and the initial 28 day dose limiting toxicity assessment period, and the second dose cohort is enrolling patients. Preliminary PK data from the first dose cohort is consistent with nonclinical modeling of our Phase 1 starting dose. We expect to report initial data from the Phase 1 portion of the trial in the second half of 2021. In addition, we plan to explore the potential clinical benefit of OP-1250 in combination with other approved agents for breast cancer, such as inhibitors of CDK4/6 and phosphatidylinositol 3-kinase alpha, or PI3Kα, which have been shown to lead to improvements in both progression-free and overall survival. In July 2020, we entered into a non-exclusive agreement with Novartis Institutes for BioMedical Research, Inc., or Novartis, to evaluate the combination of OP-1250 and Novartis' ribociclib, a CDK4/6 inhibitor, as well as alpelisib, their PI3Kα inhibitor. Under the terms of the collaboration, Novartis will be responsible for funding a capped majority of the costs for the Phase 1b clinical trial, as well as supplying their drugs.

Our team

Our Chief Technology Officer, Cyrus Harmon, Ph.D., and Chief Scientific Officer, Peter Kushner, Ph.D., co-founded the company in 2007 with the goal of discovering and developing therapies to improve the lives of women with cancer. Our management team has significant experience in oncology and in progressing products from early stage research to clinical trials, and ultimately to regulatory approval and commercialization. Together, they bring in-house expertise in medicinal chemistry, biology, translational medicine, computational biology and chemistry, in vitro and in vivo pharmacology, biomarker development and manufacturing. We have also established internal expertise in clinical development, clinical operations, pharmacovigilance, clinical pharmacology, regulatory and quality. Our Chief Executive Officer, Sean Bohen, M.D., Ph.D., was previously the Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca. Prior to AstraZeneca, Dr. Bohen held various leadership roles during his 13 years at Genentech including Senior Vice President, Early Development. Other members of the management team have held senior level positions at Neomorphic (sold to Affymetrix), Serra Pharmaceuticals (sold to Karo Bio), Genentech, BlueRock Therapeutics (sold to Bayer AG), Intellikine (sold to Takeda), Kosan Biosciences (sold to Bristol-Myers Squibb), PTC Therapeutics, Portola Pharmaceuticals (sold to Alexion), Alexion Pharmaceuticals and Elan Corporation (sold to Perrigo). We are supported by our board of directors, scientific advisory board and a leading syndicate of investors which includes Avoro Capital Advisors, funds and accounts managed by BlackRock, BVF Partners L.P., Cormorant Asset Management, Deerfield Management Company, Foresite Capital, Janus Henderson Investors, Logos Capital, OrbiMed, RA Capital Management, Surveyor Capital (a Citadel company), Venrock Healthcare Capital Partners, Vivo Capital and Wellington Management.

Our strategy

Our goal is to discover, develop and commercialize next generation targeted therapies for women's cancers. The key elements of our business strategy to achieve this goal include:

- Applying our deep understanding of nuclear receptors—particularly the ER—and mechanisms of resistance to develop novel therapeutic approaches for endocrine-driven cancers;
- Rapidly advancing our lead product candidate, OP-1250, through clinical development as a monotherapy for ER+/HER2- breast cancer;
- Establishing OP-1250 as the endocrine therapy of choice with targeted therapy combinations for the treatment of metastatic ER+ breast cancers;
- Exploring additional clinical opportunities for OP-1250, including metastatic breast cancer with brain metastases and other hormone sensitive tumors;
- Continuing to evaluate opportunities to accelerate development timelines and enhance the commercial potential of our programs in collaboration with third parties; and
- Expanding our portfolio of therapies focused on women's oncology through both internal research activities and business development efforts.

Risks related to our business

Investing in our common stock involves substantial risk. The risks described under the section titled "Risk Factors" immediately following this prospectus summary may cause us to not realize the full benefits of our strengths or may cause us to be unable to successfully execute all or part of our strategy. Some of the more significant challenges include the following:

- We have not completed any clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- Even if this offering is successful, we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs of our only product or future commercialization efforts.
- We have incurred net losses since inception, and we expect to continue to incur net losses for the foreseeable future. We expect to continue to incur increased expenses and operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval for OP-1250. In addition, we may be unable to continue as a going concern over the long-term.
- We are substantially dependent on the success of our only product candidate, OP-1250, which is currently in the early stages of clinical development. We cannot assure you that our planned clinical development programs for OP-1250 will be completed in a timely manner, or at all, or that we will be able to obtain approval for OP-1250 from the FDA, or any comparable foreign regulatory authority. If we are unable to complete development of, obtain regulatory approval for and commercialize OP-1250 in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.
- Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development. We have never completed a pivotal clinical trial or submitted a New Drug Application, or NDA, to the FDA or similar drug approval filings to comparable foreign authorities. If we are ultimately unable to obtain regulatory approval for OP-1250, we will be unable to generate product revenue and our business, financial condition, results of operations and prospects will be significantly harmed.
- Even if approved, OP-1250 may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success. The degree of

market acceptance would depend on a number of factors. If OP-1250 is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue and could significantly harm our business, financial condition, results of operations and prospects.

- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than OP-1250, or product candidates we may develop in the future, our commercial opportunities will be negatively impacted.
- We may be unable to obtain U.S. or foreign regulatory approvals and, as a result, may be unable to commercialize OP-1250 or any future product candidate we may develop.
- The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our nonclinical studies and clinical trials.
- In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth. Given the small size of our organization, we may encounter difficulties managing multiple clinical trials at the same time, which could negatively affect our ability to manage the growth of our organization, particularly as we take on additional responsibility associated with being a public company. If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize OP-1250 and any other future product candidates we may develop and, accordingly, may not achieve our research, development and commercialization goals.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. Thus, the degree of future protection for our proprietary rights is uncertain.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations, or CROs, to conduct certain aspects of our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize OP-1250 or future product candidates we may develop and our business, financial condition, results of operations and prospects could be significantly harmed.
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

Corporate information

We were initially incorporated in Delaware in August 2006 under the name CombiThera, Inc., and we commenced operations in March 2007. In March 2009, we changed our name to Olema Pharmaceuticals, Inc. Our principal executive offices are located at 512 2nd Street, 4th Floor, San Francisco, California 94107, and our telephone number is (415) 651-3316. Our website address is www.olema.com. Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference.

We use the Olema Oncology logo and other marks as trademarks in the United States and other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable

licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Implications of being an emerging growth company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm under Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments. We may take advantage of these exemptions for up to five years or until we are no longer an "emerging growth company," whichever is earlier. We will cease to be an emerging growth company prior to the end of such five-year period if certain earlier events occur, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not "emerging growth companies."

The Offering

Common stock offered by us	11,000,000 shares.
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to 1,650,000 additional shares of our common stock at the initial public offering price, less underwriting discounts and commissions.
Common stock to be outstanding immediately after this offering	38,519,738 shares (or 40,169,738 shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $191.1 million (or approximately $220.3 million if the underwriters' option to purchase additional shares of our common stock from us is exercised in full), after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to complete our ongoing Phase 1/2 monotherapy clinical trial, to advance OP-1250 through our planned Phase 1b combination trials with CDK4/6i and PI3Kα, and the remainder for other ongoing research and development activities, and for other general corporate purposes, including working capital, operating expenses and capital expenditures. See the section titled "Use of Proceeds" for additional information.
Risk factors	See the section titled "Risk Factors" beginning on page 11 and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Directed share program	At our request, the underwriters have reserved up to 5% of the shares offered by this prospectus for sale at the initial public offering price to certain individuals through a directed share program, including our directors, officers, employees and certain other individuals identified by management. The sales will be made at our direction by J.P. Morgan Securities LLC and its affiliates through a directed share program. The number of shares of our common stock available for sale to the general public in this offering will be reduced to the extent that such persons purchase such reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of our common stock offered by this prospectus. See the section titled "Underwriting" for additional information.
Nasdaq trading symbol	"OLMA"

The number of shares of our common stock to be outstanding after this offering is based on 27,519,738 shares of common stock outstanding as of September 30, 2020 (including (i) 23,765,075 shares issuable upon the conversion of all outstanding shares of our convertible preferred stock as of September 30, 2020 and (ii) 895,391 shares of unvested restricted common stock subject to repurchase as of such date), and excludes:

- 2,505,811, shares of our common stock issuable upon the exercise of outstanding stock options as of September 30, 2020, with a weighted-average exercise price of $4.14 per share;
- 2,152,080 shares of our common stock reserved for future issuance under our 2020 Equity Incentive Plan, or 2020 Plan, which became effective once the registration statement of which this prospectus forms a part was declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2020 Plan and any shares underlying outstanding stock awards granted under our 2014 Stock Plan, or 2014 Plan, that expire or are repurchased, forfeited, cancelled or withheld, as more fully described in the section titled “Executive Compensation — Equity Benefit Plans” (of which options to purchase an aggregate of 2,144,891 shares of our common stock were granted to certain of our non-employee directors, executive officers and other employees at the time of effectiveness of the 2020 Plan with an exercise price equal to the initial public offering price per share); and
- 430,416 shares of our common stock reserved for issuance under our 2020 Employee Stock Purchase Plan, or ESPP, which became effective once the registration statement of which this prospectus forms a part was declared effective, and any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP.

Unless otherwise indicated, this prospectus assumes or gives effect to:

- a 1-for-2.788 reverse stock split of our common stock and convertible preferred stock effected on November 13, 2020;
- the automatic conversion of all outstanding shares of our convertible preferred stock as of September 30, 2020 into an aggregate of 23,765,075 shares of our common stock upon the closing of this offering;
- no exercise of the outstanding options described above;
- no exercise by the underwriters of their option to purchase 1,650,000 additional shares of common stock from us in this offering; and
- the filing and effectiveness of our amended and restated certificate of incorporation immediately after the closing of this offering, and the adoption of our amended and restated bylaws upon the closing of this offering.

Summary financial data

The following tables set forth our summary financial data for the periods and as of the dates indicated. The following summary statements of operations data for the years ended December 31, 2018 and 2019 have been derived from our audited financial statements included elsewhere in this prospectus. The following summary statements of operations data for the nine months ended September 30, 2019 and 2020 and the summary balance sheet data as of September 30, 2020 have been derived from our unaudited interim condensed financial statements included elsewhere in this prospectus. The unaudited interim condensed financial statements were prepared on a basis consistent with our audited financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future and our interim results are not necessarily indicative of our expected results for the year ending December 31, 2020. You should read the following summary financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus. The summary financial data included in this section are not intended to replace the financial statements and are qualified in their entirety by our financial statements and the related notes included elsewhere in this prospectus.

	Year ended December 31,		Nine months ended September 30,	
	2018	2019	2019	2020
	(in thousands, except share and per share data)		(unaudited)	
Operating expenses:				
Research and development	$ 1,693	$ 3,920	$ 3,010	$ 7,415
General and administrative	386	403	296	3,982
Total operating expenses	2,079	4,323	3,306	11,397
Loss from operations	(2,079)	(4,323)	(3,306)	(11,397)
Other (expense) income:				
Interest income	4	7	7	59
Interest (expense)	(28)	—	–	(653)
Other income	–	–	–	1
Loss on extinguishment of convertible notes	(63)	—	—	–
Loss on remeasurement of convertible notes	(31)	—	–	–
Total other (expense) income, net	(118)	7	7	(593)
Net loss and comprehensive loss[1]	$ (2,197)	$ (4,316)	$ (3,299)	$ (11,990)
Repurchase and retirement of Series A and Series A-1 convertible preferred stock	–	–	–	(1,869)
Net loss attributable to common stockholders	$ (2,197)	$ (4,316)	$ (3,299)	$ (13,859)
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (0.87)	$ (1.66)	$ (1.27)	$ (5.29)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted[1]	2,522,577	2,593,316	2,593,316	(2,617,543)
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[1]		$ (0.60)		$ (0.98)
Weighted-average shares used to compute pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[1]		7,221,531		14,098,571

(1) See Note 11 to our financial statements included elsewhere in this prospectus for a description of how we compute basic and diluted net loss per share attributable to common stockholders and pro forma basic and diluted net loss per share attributable to common stockholders.

	As of September 30, 2020		
(in thousands)	**Actual**	**Pro forma[1]**	**Pro forma as adjusted[2]**
		(unaudited)	
Balance Sheet Data:			
Cash and cash equivalents	$127,824	$ 127,824	$ 319,808
Working capital[3]	123,814	123,814	316,385
Total assets	130,683	130,683	321,191
Total liabilities	5,273	5,273	4,686
Convertible preferred stock	148,373	–	—
Accumulated deficit	(22,964)	(22,964)	(22,963)
Total stockholders' equity (deficit)	(22,963)	125,410	316,505

(1) The pro forma column in the balance sheet data gives effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 23,765,075 shares of common stock which will occur upon the closing of this offering and the related reclassification of the carrying value of our convertible preferred stock to permanent equity upon the closing of this offering, and (ii) the filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately after the closing of this offering.

(2) The pro forma as adjusted column in the balance sheet data gives effect to (i) the items described in footnote (1) above and (ii) the issuance and sale of 11,000,000 shares of our common stock in this offering at the initial public offering price of $19.00 per share after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities. See our financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

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 prospectus, including our 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. Such risks and uncertainties may be amplified by the COVID-19 pandemic and its potential impact on our business and the global economy. 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. This prospectus also contains forward-looking statements that involve risks. See the section titled "Special Note Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks related to our financial position and need for additional capital

We have not completed any clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are a clinical-stage biopharmaceutical company and we have no products approved for commercial sale, have not generated any revenue from product sales and have incurred losses since inception. To date, we have devoted substantially all of our resources and efforts to organizing and staffing our company, business planning, executing partnerships, raising capital, discovering, identifying and developing our product candidate, OP-1250, securing related intellectual property rights and conducting nonclinical studies and initiating a Phase 1/2 clinical trial of OP-1250. We have not yet demonstrated our ability to successfully complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of successfully executing drug development activities and supporting commercial operations. If we do not adequately address these risks and difficulties or successfully make such a transition, our business, financial condition, results of operations and prospects will be significantly harmed.

Even if this offering is successful, we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs of our only product or future commercialization efforts.

Developing pharmaceutical products, including conducting nonclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses will increase in connection with our ongoing activities, particularly as we initiate and conduct clinical trials of, and seek marketing approval for, OP-1250. With only one product candidate in development, we anticipate incurring significant costs associated with the development of OP-1250. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other regulatory agencies to perform clinical trials or nonclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. In addition, if we obtain marketing approval for OP-1250, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably

estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. Following this offering, we also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of September 30, 2020, we had $127.8 million in cash and cash equivalents. Based on our current operating plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditures requirements for at least the next 24 months. Our estimate as to how long we expect the net proceeds from this offering, together with our existing cash and cash equivalents, to be able to continue to fund our operating expenses and capital expenditures requirements is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Moreover, it is particularly difficult to estimate with certainty our future expenses given the dynamic nature of our business, the COVID-19 pandemic and the macro-economic environment generally.

We plan to use the net proceeds from this offering to advance and expand our clinical and nonclinical development programs and for working capital and other general corporate purposes. Advancing the development of OP-1250 and any future product candidates we may develop will require a significant amount of capital. The net proceeds from this offering and our existing cash and cash equivalents will not be sufficient to fund all of the activities that are necessary to complete the development of OP-1250.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Adequate additional financing may not be available to us on acceptable terms, or at all. Market volatility, including as a result of the COVID-19 pandemic, could also adversely impact our ability to access capital as and when needed. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

We have incurred net losses since inception, and we expect to continue to incur net losses for the foreseeable future. In addition, we may be unable to continue as a going concern over the long-term.

We have incurred net losses in each reporting period since our inception, have not generated any revenue from product sales to date and have financed our operations principally through private financings. We have incurred net losses of $4.3 million and $2.2 million for the years ended December 31, 2019 and 2018, respectively and $12.0 million for the nine months ended September 30, 2020. We had an accumulated deficit of $10.8 million and $23.0 million as of December 31, 2019 and September 30, 2020, respectively. Our losses have resulted principally from expenses incurred in research and development of OP-1250 and from management and administrative costs and other expenses that we have incurred while building our business infrastructure. Our only product candidate, OP-1250, is in early-stage clinical trials. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing OP-1250 in one of our lead indications, we expect that we will continue to incur substantial research and development and other expenses as we continue the clinical development programs for OP-1250 in other indications.

We expect to continue to incur increased expenses and operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval for OP-1250. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. 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 working capital. In

any particular period, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

In addition, our financial statements for the year ended December 31, 2019 included elsewhere in this prospectus have been prepared assuming we will continue as a going concern. However, we have incurred losses and negative cash flows from operations. As a development stage company, we expect to incur significant and increasing losses until regulatory approval is granted for OP-1250. Regulatory approval is not guaranteed and may never be obtained. As a result, these conditions raise substantial doubt about our ability to continue as a going concern over the long-term.

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

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with our collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, OP-1250 and any future product candidates we may develop. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate revenue from product sales depends heavily on our and our current and potential future collaborators' success in:

- completing clinical and nonclinical development of product candidates and programs and identifying and developing new product candidates;
- seeking and obtaining marketing approvals for any product candidates that we develop;
- launching and commercializing product candidates for which we obtain marketing approval by establishing a sales force, marketing, medical affairs and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- achieving adequate access and reimbursement by government and third-party payors for product candidates that we develop;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for product candidates that we develop, if approved;
- obtaining market acceptance of product candidates that we develop as viable treatment options;
- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- defending against third-party interference, infringement or other intellectual property-related claims, if any; and
- attracting, hiring and retaining qualified personnel.

Even if OP-1250 or any future product candidate that we may develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the EMA or other comparable regulatory agencies to perform clinical trials or nonclinical studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

Risks related to the discovery, development and commercialization of our product candidate

We are substantially dependent on the success of our only product candidate, OP-1250, which is currently in the early stages of clinical development. If we are unable to complete development of, obtain regulatory approval for and commercialize OP-1250 in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.

Our future success is heavily dependent on our ability to timely complete clinical trials, obtain marketing approval for and successfully commercialize OP-1250, our only product candidate. We expect that a substantial portion of our efforts and expenses over the next several years will be devoted to the development of OP-1250 in our ongoing clinical trials in multiple indications. We are investing significant efforts and financial resources in the research and development of OP-1250. OP-1250 will require additional clinical development, evaluation of clinical, nonclinical and manufacturing activities, marketing approval from government regulators, and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote OP-1250 before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. Should our planned clinical development of OP-1250 in our lead indications fail to be completed in a timely manner or at all, we will need to rely on our ongoing and planned clinical development of OP-1250 in additional indications, which will require more time and resources to obtain regulatory approval and proceed with commercialization, and may ultimately be unsuccessful. We cannot assure you that our planned clinical development programs for OP-1250 will be completed in a timely manner, or at all, or that we will be able to obtain approval for OP-1250 from the FDA, EMA, or any comparable foreign regulatory authority. If we are unable to complete development of, obtain regulatory approval for and commercialize OP-1250 in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development. We have never completed a clinical trial or submitted a New Drug Application, or NDA, to the FDA or similar drug approval filings to comparable foreign authorities. If we are ultimately unable to obtain regulatory approval for OP-1250, we will be unable to generate product revenue and our business, financial condition, results of operations and prospects will be significantly harmed.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of nonclinical studies and early clinical trials of OP-1250 and any future product candidates we may develop may not be predictive of the results of subsequent clinical trials. We have a limited operating history and to date have not demonstrated our ability to complete large scale clinical trials.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials. In addition to the safety and efficacy traits of any product candidate, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or any potential future collaborator may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval.

Our future clinical trials may not be successful. If any product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business, financial condition, results of operations and prospects may be significantly harmed. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including

changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the dropout rate among clinical trial participants. Patients treated with OP-1250 or product candidates we may develop in the future may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to OP-1250 or product candidates we may develop. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market OP-1250 or any future product candidates we may develop.

We do not know whether our current clinical trial of OP-1250 or any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market OP-1250 or any future product candidates we may develop. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. If we are unable to bring OP-1250 or any future product candidates to market, our ability to create long-term shareholder value will be limited.

In addition, we may rely in part on nonclinical, clinical and quality data generated by contract research organizations, or CROs, and other third parties for regulatory submissions for OP-1250. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, our development programs may be significantly delayed, and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase.

Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in nonclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable foreign regulatory authority approval. We cannot guarantee that the FDA or foreign regulatory authorities will interpret trial results as we do, and more trials could be required before we are able to submit an application seeking approval of OP-1250 or any future product candidates we may develop. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of OP-1250 or any future product candidates we may develop. Even if regulatory approval is secured for OP-1250, the terms of such approval may limit the scope and use of OP-1250, which may also limit its commercial potential. Furthermore, the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA, EMA or comparable foreign regulatory authorities delaying, limiting or denying approval of OP-1250, including and any other indication we are seeking for approval under OP-1250.

The regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for OP-1250 or any future product candidates we may develop, our business, financial condition, results of operations and prospects will be significantly harmed.

The time required to obtain approval by the FDA, EMA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Applications for OP-1250 could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;

- the FDA, EMA or other comparable foreign regulatory authorities may determine that OP-1250 is not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials of OP-1250 may not be sufficient to support the submission of a NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that OP-1250's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market OP-1250, which would significantly harm our business, financial condition, results of operations and prospects.

In addition, even if we obtain approval of OP-1250 for a lead indication, regulatory authorities may not approve OP-1250 for other indications, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy, or REMS. Certain regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or may approve OP-1250 with a label that does not include the labeling claims necessary or desirable for successful. In addition, regulatory authorities in certain countries may not approve the price we intend to charge for the product we develop. If we are unable to obtain regulatory approval of OP-1250, or if regulatory approval is limited, our business, financial condition, results of operation and prospects will be significantly harmed.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of OP-1250 or any future product candidate we may develop. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA, EMA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards, or IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;

- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- delays in enrollment by subjects, or completion of the trial by subjects, due to the COVID-19 pandemic;
- subjects choosing an alternative treatment for the indication for which we are developing OP-1250, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- regulatory authorities imposing a clinical hold;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- shutdowns, either temporarily or permanently, of any facility manufacturing OP-1250 or any future product candidate we may develop or any of their components, including by order from the FDA, EMA or comparable foreign regulatory authorities due to violations of current good manufacturing practice, or cGMP, regulations or other applicable requirements, or infections or cross-contaminations of OP-1250 or any future product candidate we may develop in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA, EMA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for OP-1250 or product candidates we may develop in the future, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in

healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

If we experience delays in the completion of, or termination of, any clinical trial of OP-1250 or any product candidates we may develop in the future, the commercial prospects of OP-1250 or any product candidates we may develop in the future will be harmed, and our ability to generate product revenues from OP-1250 or any product candidates we may develop in the future will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down OP-1250's or any product candidates we may develop in the future's development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of OP-1250 or any product candidates we may develop in the future. Any delays in our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize OP-1250 or any product candidates we may develop in the future and our competitors may be able to bring products to market before we do, and the commercial viability of OP-1250 or any product candidates we may develop in the future could be significantly reduced. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

Because we are pursuing a variety of target indications for OP-1250, we may expend our limited resources to pursue a particular indication and fail to capitalize on indications or additional product candidates that may be more profitable or for which there is a greater likelihood of success.

We are currently focused on pursuing a variety of target indications for OP-1250, and we have expended, and plan to continue to expend, significant resources to pursue these and other indications for OP-1250. In addition, we may in the future spend our resources on other research programs and product candidates for specific indications that ultimately do not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Because we have limited financial and managerial resources, we must focus our research and development efforts on those product candidates and specific indications that we believe are the most promising. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications 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, which will significantly harm our business, financial condition, results of operations and prospects.

Even if approved, OP-1250 may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if OP-1250 receives regulatory approval, it may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance would depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of OP-1250, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;

- our pricing and the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- the availability of OP-1250 for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to OP-1250 or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

If OP-1250 is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue and could significantly harm our business, financial condition, results of operations and prospects.

If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for OP-1250, or any future product candidate we may develop, if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Additionally, certain clinical trials for future product candidates may be focused on indications with relatively small patient populations, which may further limit enrollment of eligible patients or may result in slower enrollment than we anticipate. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Enrollment of patients in our clinical trials and maintaining patients in our ongoing clinical trials may be delayed or limited as our clinical trial sites limit their onsite staff or temporarily close as a result of the COVID-19 pandemic. In addition, patients may not be able to visit clinical trial sites for dosing or data collection purposes due to limitations on travel and physical distancing imposed or recommended by federal or state governments or patients' reluctance to visit the clinical trial sites during the pandemic. These factors resulting from the COVID-19 pandemic could delay the anticipated readouts from our clinical trials and ultimately delay future regulatory submissions.

Patient enrollment may also be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as OP-1250, or any future product candidate we may develop, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment for any of our clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;

- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- continued enrollment of prospective patients by clinical trial sites; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

Our inability to enroll and maintain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for OP-1250 or any future product candidate we may develop and jeopardize our ability to obtain marketing approval for the sale of OP-1250 or any product candidate we may develop in the future. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

We intend to develop OP-1250, and may develop future product candidates, in combination with other therapies, which exposes us to additional risks.

We intend to develop OP-1250, and may develop other future product candidates, in combination with one or more other approved or unapproved therapies to treat cancer or other diseases. For example, we plan to initiate a Phase 1b clinical trial of OP-1250 as part of combination therapy with independent arms investigating its potential with a cyclin-dependent kinase 4 and 6 inhibitor and with a phosphatidylinositol 3-kinase alpha inhibitor.

Even if OP-1250, or any future product candidate we develop, were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with OP-1250, or any future product candidate we may develop, are replaced as the standard of care for the indications we choose for OP-1250 or any future product candidate we may develop, the FDA, EMA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own product, if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate OP-1250 or future product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell OP-1250, or any future product candidate we may develop, in combination with an unapproved cancer therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved cancer therapies face the same risks described with respect to OP-1250 currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA, EMA or comparable foreign regulatory approval.

If the FDA, EMA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with OP-1250 or future product candidates we may develop, we may be unable to obtain approval of or market such combination therapy.

The incidence and prevalence for target patient populations of OP-1250 are based on estimates and third-party sources. If the market opportunities for OP-1250, or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates

in making decisions regarding our drug development strategy, including acquiring or in-licensing product candidates and determining indications on which to focus in nonclinical or clinical trials.

The incidence and prevalence for target patient populations of OP-1250 are based on estimates and third-party sources. These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, acceptance of our drugs by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to. If the market opportunities for OP-1250, or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

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

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

From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock after this offering.

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

If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, OP-1250 or any future product candidates we may develop may be harmed, which could significantly harm our business, financial condition, results of operations and prospects.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than OP-1250, or product candidates we may develop in the future, our commercial opportunities will be negatively impacted.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors

have developed, are developing or may develop products, product candidates and processes competitive with OP-1250. Any product candidate that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are attempting to develop OP-1250. Products we may develop in the future are also likely to face competition from other products and therapies, some of which we may not currently be aware. In addition, OP-1250 and any product candidate that we may develop in the future may need to compete with off-label drugs used by physicians to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with OP-1250 and any product candidate that we may develop in the future.

In particular, there is intense competition in the fields of women's cancer which we are pursuing. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, universities and other research institutions. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates.

If we are successful in developing OP-1250, it may compete against existing products and product candidates in development, to the extent any such product candidates are approved, for the treatment of estrogen receptor-positive, or ER+, breast cancer, including certain complete estrogen receptor antagonist, or CERAN, therapies, such as RG6171 being developed by Roche Holding AG/Genentech, Inc., or Genentech, fulvestrant, marketed as Faslodex® by AstraZeneca PLC, or any generic equivalents of Faslodex® that may be developed, AZD9833 being developed by AstraZeneca PLC, SAR439859 being developed by Sanofi S.A. and LY3484356 being developed by Eli Lilly and Co., as well as certain selective estrogen receptor degrader, or SERD, or SERD therapies that are not CERANs, such as ZN-c5 being developed by Zentalis Pharmaceuticals, Inc., elacestrant being developed by Radius Health, Inc., ARV-471 being developed by Arvinas, Inc., rintodestrant (G1T48) being developed by G1 Therapeutics, Inc. and H3B-6545 being developed by H3 Biomedicines, a subsidiary of Eisai Co., Ltd.

We have chosen to initially address well-validated biochemical targets, and therefore expect to face competition from existing products and products in development. There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidate that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing products in our field before we do.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, receive greater levels of reimbursement than products we may develop receive or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if OP-1250 or other product candidates we may develop in the

future achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or OP-1250 or product candidates we may develop in the future obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our product we may develop, if approved, would be adversely affected.

Changes in methods of OP-1250 manufacturing or formulation may result in additional costs or delay.

As OP-1250 progresses through nonclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause OP-1250 to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of OP-1250 and jeopardize our ability to commercialize OP-1250, if approved, and generate revenue.

Any product candidate we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. If we obtain marketing approval of OP-1250, or any future product candidate we may develop, sales of such product will depend substantially, both in the United States and internationally, on the extent to which the costs of the product will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only at inadequate levels, we may not be able to successfully commercialize OP-1250 or any future product candidates we may develop. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our product to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and requiring substitutions of generic products and/or biosimilars. Increasingly, third-party

payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our product. Nonetheless, OP-1250 or any future product candidates we may develop may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as OP-1250 or any future product candidates we may develop. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of OP-1250 or any future product candidates we may develop to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for OP-1250 or any future product candidates we may develop. Accordingly, in markets outside the United States, the reimbursement for any product that we commercialize may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates that we commercialize from third-party payors, the adoption of those products and potential sales revenue would be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for a product for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Guidelines and recommendations published by various organizations can reduce the use of OP-1250 or any future product candidates we may develop.

Government agencies promulgate regulations and guidelines directly applicable to us and to OP-1250 or any future product candidates we may develop. In addition, professional societies, such as practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of OP-1250 or any future product candidates we may develop or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of OP-1250 or any future product candidates we may develop.

Risks related to regulatory approval and other legal compliance matters

We may be unable to obtain U.S. or foreign regulatory approvals and, as a result, may be unable to commercialize OP-1250 or any future product candidate we may develop.

OP-1250 is, and any product candidate we develop in the future will be, subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy,

approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous nonclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. We cannot provide any assurance that OP-1250 or any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not conducted, managed or completed large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority. The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable, and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA, EMA or other comparable foreign regulatory authorities use when evaluating clinical trial data can, and often does, change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA, EMA or other comparable foreign regulatory authorities' policies during the period of drug development, clinical trials and FDA, EMA or other comparable foreign regulatory authorities' regulatory review.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we developing and seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of approving a NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include 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 significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We may also become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials and manufacturing of OP-1250. The foreign regulatory approval process varies among countries, and generally includes 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.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage, such inability could significantly harm our business, financial condition, results of operations and prospects.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our product, our manufacturing processes and facilities or our marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of our product or more serious enforcement action, limitations on the approved indications for which it may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing OP-1250, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain

sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could significantly harm our business, financial condition, results of operations and prospects.

OP-1250 and any future product candidates we develop may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with the use of OP-1250 or any future product candidates we may develop. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by OP-1250 or any future product candidates we may develop could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or other comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

If OP-1250 or any future product candidates we may develop are associated with undesirable side effects or have unexpected characteristics in nonclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete a trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may significantly harm our business, financial condition, results of operations and prospects.

Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our nonclinical studies or previous clinical trials. OP-1250 or any future product candidates we may develop, may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, if OP-1250 or any future product candidates we may develop, are used in combination with other therapies, OP-1250 or any future product candidates we may develop may exacerbate adverse events associated with the therapy and it may not be possible to determine whether it was caused by our product or the one with which it was combined. Patients treated with OP-1250 or any future candidates we may develop, may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to OP-1250 or any future product candidates we may develop, but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

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

Further, if OP-1250 obtains marketing approval, toxicities associated with OP-1250 and not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials,

additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether OP-1250 will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on nonclinical studies or early-stage clinical trials.

The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We may choose to conduct international clinical trials in the future. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the United States population and United States medical practice; (2) the trials are performed by clinical investigators of recognized competence and pursuant to current GCP requirements; and (3) the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in OP-1250 or any future product candidates we may develop not receiving approval for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of OP-1250, or any product candidate we develop in the future, in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of OP-1250, or any product candidate we develop in the future, in other jurisdictions.

Obtaining and maintaining regulatory approval of OP-1250, or any product candidate we develop in the future, in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA, EMA or other foreign regulatory authority grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate 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 product is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of OP-1250, or any product candidate we develop in the future, will be harmed.

Even if OP-1250, or any product candidate we develop in the future, receives regulatory approval, it will be subject to significant post-marketing regulatory requirements and oversight.

Any regulatory approvals that we may receive for OP-1250, or any product candidate we develop in the future, will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups,

warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve OP-1250, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or applicable foreign regulatory authorities approve OP-1250 or any product candidate we develop in the future, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for OP-1250 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 on-going compliance with cGMPs and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize OP-1250, or any product candidate we may develop in the future, and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of OP-1250 or any product candidate we may develop in the future. 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.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current U.S. administration may impact our business and industry. Namely, the current U.S. administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If

these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, it may significantly harm our business, financial condition, results of operations and prospects.

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

If OP-1250 or any future product candidate we may develop is approved for marketing, and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as OP-1250 or any future product candidates we may develop, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for OP-1250 or any future product candidates we may develop, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of OP-1250 or any future product candidates we may develop, if approved, we could become subject to significant liability, which would significantly harm our business, financial condition, results of operations and prospects.

Disruptions at the FDA, EMA, applicable foreign regulatory authorities, the U.S. Securities and Exchange Commission, or the SEC, and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could significantly harm our business, financial condition, results of operations and prospects.

The ability of the FDA, EMA or any applicable foreign regulatory authority to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA, EMA or any applicable foreign regulatory authority's ability to perform routine functions. Average review times at the agencies have fluctuated in recent years as a result and could be delated by the COVID-19 pandemic or other factors. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products through April 2020. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon closing of this offering and in our operations as a public company, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may attempt to secure approval from the FDA, EMA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional nonclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, EMA or comparable foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA, EMA or comparable foreign regulatory authorities may seek to withdraw any accelerated approval.

We may in the future seek an accelerated approval for OP-1250 or future product candidates we may develop. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verity and describe the drug's clinical benefit. Third-party payors may refuse to provide coverage or reimbursement for the drug until the confirmatory studies are complete. Additionally, if such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval for OP-1250, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for OP-1250, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for OP-1250 would result in a longer time period to commercialization of such product candidate, could increase the cost of development of OP-1250 and could harm our competitive position in the marketplace.

We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of OP-1250 or any future product candidates we may develop. 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.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was passed, which substantially changes the

way healthcare is financed by both the government and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. There remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed. On December 22, 2017, President Trump signed into law federal tax legislation commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018 among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case, although it is unclear when a decision will be made or how the Supreme Court will rule. In addition, there may be other efforts to challenge, repeal or replace the ACA. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business, financial condition, results of operations and prospects.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 unless additional congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, 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 potential customers for our drugs, if approved, and accordingly, our business.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, at the federal level, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly

out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration's budget proposal for the fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Further, on July 24, 2020, President Trump signed four additional Executive Orders designed to reduce the cost of drugs. Although a number of these and other measures may require additional authorization 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. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize OP-1250 or any future product candidates we may develop. It is possible that additional governmental action is taken to address the COVID-19 pandemic.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of OP-1250 or any future product candidates we may develop, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and privacy and security laws (including health information privacy and security laws), which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of our product candidate for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal
- healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from,

among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, also imposes obligations, including mandatory contractual terms, certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians, as defined by such law and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives. The information reported is publicly available on a searchable website, with disclosure required annually; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Some state laws require biotechnology companies to report information on the pricing of certain drug products. Some state and local laws require the registration of pharmaceutical sales representatives.

State and foreign laws also 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. For instance, the collection and use of health data in the European Union is governed by the General Data Protection Regulation, or the GDPR, which extends the enforcement of European Union data protection law to non-European Union entities under certain conditions, tightens existing European Union data protection principles, creates new obligations for companies and new rights for individuals. In particular, the GDPR includes obligations and restrictions concerning the consent and rights of individuals to whom the personal data relates, the transfer of personal data out of the European Economic Area, or EEA, or the United Kingdom, security breach notifications and the security and confidentiality of personal data. In addition to introducing new data protection requirements in the European Union, the GDPR also established potential fines for noncompliant companies. Failure to comply with the GDPR may result in substantial fines up to the greater of €20 million or 4% of annual global revenue and other administrative penalties. Such fines are in addition to any civil litigation claims by data subjects. European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which contributes to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices is often updated or otherwise revised. The GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required

to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and if our efforts to comply with GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect our business in the European Union.

European data protection laws also generally prohibit the transfer of personal data from Europe, including the EEA, United Kingdom and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards used for transfers of personal data from the European Union to the United States, namely, the Privacy Shield framework administered by the U.S. Department of Commerce, was recently invalidated by a decision of the European Union's highest court. The same decision also cast doubt on the ability to use one of the primary alternatives to the Privacy Shield, namely, the European Commission's Standard Contractual Clauses, to lawfully transfer personal data from Europe to the United States and most other countries. At present, there are few if any viable alternatives to the Privacy Shield and the Standard Contractual Clauses. To the extent that we were to rely on the EU-U.S. Privacy Shield Framework or the Standard Contractual Clauses, we will not be able to do so in the future, which could increase our costs and limit our ability to process personal data from the European Union.

Further, the vote in the United Kingdom in favor of exiting the European Union, referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, while the Data Protection Act of 2018, that "implements" and complements the GDPR achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under GDPR. During the period of "transition" (i.e., until December 31, 2020), European Union law will continue to apply in the United Kingdom, including the GDPR, after which the GDPR will be converted into United Kingdom law. Beginning in 2021, the United Kingdom will be a "third country" under the GDPR. We may, however, incur liabilities, expenses, costs, and other operational losses under GDPR and applicable European Union Member States and the United Kingdom privacy laws in connection with any measures we take to comply with them.

In addition, on June 28, 2018, the State of California enacted the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information of consumers or households. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities and may increase our compliance costs and potential liability. The CCPA was amended in September 2018 and November 2019, and it is possible that further amendments will be enacted, but even in its current form it remains unclear how various provisions of the CCPA will be interpreted and enforced. New legislation proposed or enacted in Illinois, Massachusetts, Nevada, New Jersey, New York, Rhode Island, Washington and other states, and a proposed right to privacy amendment to the Vermont Constitution, imposes, or has the potential to impose, additional obligations on companies that collect, store, use, retain, disclose, transfer and otherwise process confidential, sensitive and personal information, and will continue to shape the data privacy environment nationally. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products and services involving data are offered, all of which could significantly harm our business, financial condition, results of operations and prospects.

Many statutory requirements, both in the United States and abroad, include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. For example, laws in all 50 U.S. states and the District of Columbia require businesses to provide notice to consumers whose personal information has been disclosed as a

result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify customers or other counterparties of a security breach. Although we may have contractual protections with our third-party service providers, contractors and consultants, any actual or perceived security breach could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation and application of health-related and data protection laws, regulations, standards and other obligations are still uncertain, and often contradictory and in flux, it is possible that the scope and requirements of these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country and our operations or business practices may not comply with these regulations in each country.

In addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with customers and have a material adverse effect on our business.

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

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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities.

Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. 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 significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could significantly harm our business, financial condition, results of operations or prospects.

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

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological 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 commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidate on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act, or the FCPA, and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business.

In addition, our product and activities may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our product, or our failure to obtain any required import or export authorization for our product, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our product may create delays in the introduction of our product in international markets or, in some cases, prevent the export of our product to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or product targeted by such regulations, could result in decreased use of our product by, or in our decreased ability to export our product to existing or potential customers with international operations. Any decreased use of our product or limitation on our ability to export or sell access to our product would likely significantly harm our business, financial condition, results of operations and prospects.

Risks related to employee matters, managing our growth and other risks related to our business

The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our nonclinical studies and clinical trials.

In December 2019, a novel strain of the coronavirus disease, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and, as of September 2020, has spread to a number countries, including the United States. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees

continuing their work outside of our offices and limited the number of staff in any given research and development laboratory. As a result of the COVID-19 pandemic, we experienced some delays in setting up our current Phase 1/2 clinical trial and in clinical site initiation, including delays in recruiting clinical site investigators and clinical site staff, which we may experience again in the future. Additionally, we may experience further disruptions that could severely impact our business, nonclinical studies and clinical trials, including:

- delays or difficulties in enrolling and retaining patients in our clinical trials;
- difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of OP-1250 from our contract manufacturing organizations, or CMO, due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in nonclinical studies due to restricted or limited operations at our laboratory facility;
- limitations on employee resources that would otherwise be focused on the conduct of our nonclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced discovery and clinical activities.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak impacts our business, nonclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees and key consultants.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, as well as the other members of our scientific and clinical teams, including certain key consultants. For example, Dr. Pamela Klein, our Chief Medical Officer, is a consultant and not an employee. As a result, Dr. Klein may choose to reduce the amount of time she allocates to us, or to terminate her relationship with us, at any time and for any reason, which could impede the achievement of our research, development and commercialization objectives and significantly harm our business, financial condition, results of operations and prospects.

Furthermore, although we have employment offer letters with each of our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or employees. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is

intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize OP-1250 or any other product candidate will be limited and the potential for successfully growing our business will be harmed.

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market OP-1250 or any product candidate we may develop in the future, we may not be able to successfully sell or market OP-1250 or any future product candidate we may develop that obtain regulatory approval.

We currently do not have, and have never had, a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market OP-1250 or any future product candidate we may develop. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize OP-1250 or any product candidate we may develop in the future will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of OP-1250 or any product candidate we may develop in the future that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize OP-1250 or any product candidate we may develop in the future which may receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for a product candidate, which we may license to others, we will rely on the assistance and guidance of those collaborators. For any product candidates for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize OP-1250, or any future product candidate we may develop, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe OP-1250 or any future product candidates we may develop and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of OP-1250 or any future product candidate we may develop. We may not be able to build an

effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of OP-1250 or any future product candidate we may develop, we may not generate revenues from such product candidate or be able to reach or sustain profitability.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of November 16, 2020, we had 22 employees, 21 of whom were full-time, including nine employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA, EMA and other comparable foreign regulatory agencies' review process for OP-1250 and any other future product candidates we may develop, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

In addition, we expect to be conducting multiple clinical trials of OP-1250 for several different indications concurrently. Given the small size of our organization, we may encounter difficulties managing multiple clinical trials at the same time, which could negatively affect our ability to manage growth of our organization, particularly as we take on additional responsibility associated with being a public company. Our future financial performance and our ability to successfully develop and, if approved, commercialize, OP-1250 and any other future product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of OP-1250 and any other future product candidates we may develop or otherwise advance our business. We cannot assure you that we will be able to manage our existing third party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize OP-1250 and any other future product candidates we may develop and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors, consultants, collaborators or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of preventative and detective security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants, collaborators and third-party

service providers, are vulnerable to damage or interruption from a variety of sources, including computer viruses, unauthorized access, accidental acts or omissions by those with authorized access, natural disasters, terrorism, war, telecommunication and electrical failure, and cybersecurity threats (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information). The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies.

If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws, as applicable, such as HIPAA, CCPA, HITECH and GDPR), it could result in a material disruption of our drug discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We also rely on third parties to manufacture OP-1250, and similar events relating to their computer systems could also have a material adverse effect on our business. We may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of OP-1250 could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our product in the European member states.

We intend to seek approval to market OP-1250 in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for OP-1250, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of OP-1250. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of OP-1250 will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for OP-1250 and may be affected by existing and future healthcare reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order

or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including the EEA, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of OP-1250 to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for our product. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our product is unavailable or limited in scope or amount, our potential revenues from sales and the potential profitability of OP-1250 in those countries would be negatively affected.

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

Our operations, and those of our suppliers, CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, public health pandemics or epidemics (including, for example, the outbreak of COVID-19), and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations, increase our costs and expenses and significantly harm our business, financial condition, results of operations and prospects

Our ability to develop OP-1250 or any future product candidates we may develop could be disrupted if our operations or those of our suppliers are affected by man-made or natural disasters or other business interruptions. Our corporate headquarters are located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and business could suffer in the event of a major earthquake, fire or other natural disaster.

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

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law. Under the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security, or CARES, Act signed into law on March 27, 2020, NOLs arising in tax years beginning after December 31,

2017, and before January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss, and NOLs arising in tax years beginning after December 31, 2020 may not be carried back. Moreover, under the Tax Act as modified by the CARES Act, federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of current year taxable income for tax years beginning on or after December 31, 2020. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in our ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of this offering or subsequent shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in the ownership. Our ability to utilize those NOLs could be limited by an "ownership change" as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations.

A variety of risks associated with marketing OP-1250 or any future product candidate we may develop internationally could significantly harm our business, financial condition, results of operations and prospects.

We plan to seek regulatory approval of OP-1250 or any future product candidates we may develop outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may significantly harm our business, financial condition, results of operations and prospects.

Risks related to our intellectual property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for OP-1250, any future product candidates that we may

develop and technologies related to their various uses. We generally seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad related to OP-1250, our proprietary technologies, and their manufacture and uses that are important to our business, as well as inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. We may also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties. If we or our potential licensors are unable to obtain or maintain patent protection with respect to OP-1250, proprietary technologies and their uses, our business, financial condition, results of operations and prospects could be significantly harmed.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Moreover, in the future, some of our owned patents and patent applications, or any future licensed patents or patent applications, may be co-owned with third parties. If we are unable to obtain exclusive licenses to any such co-owners' interest in such patents or patent applications, then such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. Thus, the degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to OP-1250 or any future product candidates we may develop could significantly harm our business, financial condition, results of operations and prospects.

We cannot be certain that the claims in our U.S. pending patent applications, and corresponding international patent applications, will be considered patentable by the United States Patent and Trademark Office, or USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patent(s) will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting OP-1250 or any future product candidates we may develop by obtaining and defending patents. These risks and uncertainties include the following:

- patent applications must be filed in advance of certain events (*e.g.,* third party filings, certain sales or offers for sale, or other activities that might be legally deemed to be public disclosures) and we might not be aware of such events or otherwise might not succeed in filing applications before they occur;
- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection, for example, if patentable aspects are publicly disclosed, by us or a third party, such as by public use, sale or offer for sale, or publication.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Further, although we require our employees, commercial contractors, and certain consultants and investigators to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them while in our employ, we cannot guarantee that we have entered into such agreements with each party, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach such agreements and claim ownership in intellectual property that we believe is owned by us. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Should any of the above events occur, it could significantly harm our business, financial condition, results of operations and prospects.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent positions of biopharmaceutical companies generally are highly uncertain, involve complex legal and factual questions for which important legal principles remain unsolved and have been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect OP-1250 or which effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted after issuance. Legal standards relating to valid and enforceable claim scope are unsettled in the United States and elsewhere and disputes challenging or re-defining scope are common in the biopharmaceutical industry. Even if patent applications we own or in-license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether OP-1250 or any future product candidates we may develop will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative

technologies or products in a non-infringing manner which could significantly harm our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad.

The process by which patent applications are examined and considered for issuance as patents involves consideration by the relevant patent office of "prior art" relative to the invented technology. Different countries have different rules about what information or events can be considered "prior art," and different requirements regarding when a patent application must be filed relative to any particular piece of potential prior art. Moreover, legal decisions can re-interpret or change whether particular information or events are considered to be "prior art." Still further, in the United States, patent applicants are required to notify the USPTO of any material "prior art" of which they are aware for the patent examiner to consider in addition to independent searches that the patent examiner is required to do. Also, in the United States and certain other jurisdictions, third parties are entitled to submit prior art to patent offices for consideration during examination.

We may not be aware of certain relevant prior art, may fail to identify or timely cite certain prior art, or may not be able to convince a patent examiner that our patent(s) should issue in light of the art. Also, we cannot be certain that all relevant art will be identified during examination of a patent application so that, even if a patent issues, it may be susceptible to challenge that it is not valid over art that was not considered during its examination.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or other jurisdictions, or become involved in post-grant challenges such as opposition, derivation, revocation, reexamination, post-grant review, or PGR, and *inter partes* review, or IPR, or other similar proceedings, or in litigation, challenging our patent rights, including by challenging the validity or the claim of priority of our patents. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize OP-1250 or any future product candidates we may develop and compete directly with us, without payment to us. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of OP-1250 or any future product candidates we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, including art of which we were unaware, and art which was not raised during prosecution of any of our patent applications. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would significantly impact our business, financial condition, results of operations and prospects. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates or could embolden competitors to launch products or take other steps that could disadvantage us in the marketplace or draw us into additional expensive and time consuming disputes. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

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

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

- we may not be able to detect infringement of our issued patents;
- others may be able to develop products that are similar to OP-1250, or any future product candidates we may develop, but that are not covered by the claims of the patents that we may in-license in the future or own;

- our competitors may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell OP-1250 or any future product candidates we may develop;
- we, or our current or future collaborators or license partners, might not have been the first to make the inventions covered by the issued patents or patent application that we may in-license in the future or own;
- we, or our current or future collaborators or license partners, might be found not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we may in-license in the future or own will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents, for which we are not aware;
- issued patents that we hold rights to may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- issued patents may not have sufficient term or geographic scope to provide meaningful protection;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

Our commercial success depends significantly on our ability to operate without infringing, misappropriating or otherwise violating the patents and other proprietary rights of third parties. Claims by third parties that we infringe, misappropriate or otherwise violate their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement, misappropriation or other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. A finding by a court or administrative body that we infringe the claims of issued patents owned by third parties could preclude us from commercializing OP-1250 or any future product candidates we may develop.

Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import OP-1250 or any future product candidates we may develop and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, and proceedings, such as oppositions, reexaminations, IPR proceedings and PGR proceedings, before the USPTO and/or corresponding foreign patent offices. In addition, many companies in intellectual property-dependent industries, including the biopharmaceutical industry, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous third-party U.S. and foreign issued patents and pending patent applications may exist in the fields in which we are developing OP-1250 or any future product candidates we may develop. There may be third-party patents or

patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of OP-1250 or any future product candidates we may develop. For example, we are aware of certain third party patent applications and patents in the United States and abroad that include disclosure of chemical structures sharing certain similarities with OP-1250. It is possible that one or more of such third parties could pursue patent claims or assert patent claims that allegedly encompass OP-1250.

It is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may be unable to develop, manufacture, market, sell and commercialize products or services or perform research and development or other activities covered by these patents. In the event that any of these patents were to issue and be asserted against us, we believe that we would have defenses against any such assertion, including that such patents are not valid. However, if such defenses to such assertion were unsuccessful, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents. We could also be required to obtain a license to such patents, which may not be available on commercially reasonable terms or at all. If we are unable to obtain such a license, we could be precluded from commercializing any product candidates that were ultimately held to infringe such patents.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that OP-1250, or any future product candidates we may develop, may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of OP-1250, or any future product candidates we may develop, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that OP-1250 or any future product candidates we may develop may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Still further, we cannot rely on our experience that third parties have not so far alleged that we infringe their patent rights, as provisions of U.S. patent laws provide a safe harbor from patent infringement for therapeutic products under clinical development. If and when we submit an NDA that safe harbor will expire.

Any claims of patent infringement, misappropriation or other violations asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing OP-1250 or any future product candidates we may develop;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Any patent-related legal action against us claiming damages or seeking to enjoin commercial activities relating to our products, or processes could subject us to significant liability for damages, including treble damages if we

were determined to willfully infringe, and require us to obtain a license to manufacture or market OP-1250 or any future product candidates we may develop. 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. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or a future strategic partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign OP-1250 or any future product candidates we may develop processes to avoid infringement, if necessary.

An adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing OP-1250 or any future product candidates we may develop, which could significantly harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing OP-1250 and future product candidates and technologies.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise significantly harm our business, financial condition, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights from third parties for that we identify as necessary for OP-1250 through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights.

While we may have issued patents that cover OP-1250, it is possible that third parties may have blocking patents that prevent us from marketing, manufacturing or commercializing our own patented products and practicing our own patented technology.

We may be unsuccessful in acquiring or in-licensing compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for practicing inventions claimed by our patents, including the manufacture, sale and use of OP-1250 and any future product candidates we may develop. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could significantly harm our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors or other third parties may infringe, misappropriate or otherwise violate our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement or other intellectual property claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we may in-license in the future or own is not valid, is unenforceable, and/or is not

infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our owned patents or future in-licensed patents do not cover the technology in question. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at OP-1250 or any future product candidates we may develop, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include 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/or unenforceability is unpredictable, and prior art could render our patent invalid. There is no assurance that all potentially relevant prior art relating to our patent and patent applications has been found. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patent and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would significantly harm our business, financial condition, results of operations and prospects.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could significantly harm our business, financial condition, results of operations and prospects.

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party.

Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring OP-1250 or any future product candidates to market. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our licensors and the enforcement or defense of our issued patents or those of our licensors.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 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 such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we may not be certain that we or our licensors are the first to either (1) file any patent application related to OP-1250 or any future product candidate we may develop or (2) invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including PGR, IPR and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our licensors and the enforcement or defense of our issued patents or those of our licensors, all of which could significantly harm our business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect OP-1250 or any future product candidates we may develop.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish our ability to protect our inventions, obtain,

maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property. Such changes may also increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

Further, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. 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 would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future. Any of the foregoing could significantly harm our business, financial condition, results of operations, and prospects.

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

It is possible that we do not perfect ownership of all patents, patent applications or other intellectual property. This possibility includes the risk that we do not identify all inventors, or identify incorrect inventors, which may lead to claims disputing inventorship or ownership of our patents, patent applications or other intellectual property by former employees or other third parties. There is also a risk that we do not establish an unbroken chain of title from inventors to us. Errors in inventorship or ownership can sometimes also impact priority claims. If we were to lose ability to claim priority for certain patent filings, intervening art or other events may preclude us from issuing patents.

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could significantly harm our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on OP-1250 or any future product candidates we may develop for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but there can be no assurance that any such extensions will be obtained, and the life of a patent, and the protection it affords, is limited. Even if patents covering OP-1250 or any future product candidates we may develop are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In the United States, patent term can be adjusted due to delays that occur during examination of patent applications, which may extend the term of a patent beyond 20 years. There is a risk that we may take action that detracts from any accrued patent term adjustment.

It is necessary to pay certain maintenance fees, also referred to as annuities or renewal fees in some countries, throughout the lifetime of a patent at regular intervals. Failure to pay these fees can cause a granted patent to prematurely expire, without an opportunity for revival. There is a risk that we may be unable to maintain patent protection for certain patents in all markets due to finite availability of resources.

Any of the foregoing could significantly harm our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension for OP-1250 or any future product candidates we may develop, our business, financial condition, results of operations and prospects may be significantly harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of OP-1250 or any future product candidates we may develop, one or more of our U.S. patents or those of our licensors may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of OP-1250 or any future product candidates we may develop. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be significantly harmed. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and nonclinical data and launch their product earlier than might otherwise be the case.

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

Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may 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 will 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 infringing products may compete with OP-1250 or any future product candidates we may develop, without any available recourse.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals. As a result, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Because the legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceutical products, it could be difficult for us to stop the infringement, misappropriation or violation of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our intellectual property and other proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of being invalidated or interpreted narrowly, could put our patent applications or the patent applications of our licensors

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.

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or patent applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, potential competitors might be able to enter the market with similar or identical products or technology, which could significantly harm our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business, financial condition, results of operations and prospects could be significantly harmed.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business, financial condition, results of operations and prospects may be significantly harmed. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could significantly harm our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business, financial condition, results of operations, prospects and competitive position would be significantly harmed.

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties,

and confidential information and inventions agreements with employees, consultants and advisors, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology or processes. Further, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, or claim ownership in intellectual property that we believe is owned by us. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, 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 inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. Any of the foregoing could significantly harm our business, financial condition, results of operations and prospects.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, lessees of shared multi-company property and other third parties. Many of our employees and consultants were previously employed at, or may have previously provided or may be currently providing consulting services to, other biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may become subject to litigation where a third party asserts that we or our employees or consultants inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing OP-1250 or any future product candidates or technologies we may develop. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, and cause us to lose valuable intellectual property rights or personnel, which could significantly harm our business, financial condition, results of operations and prospects. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can. 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. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise significantly harm our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our technology and product candidate may be subject, in part, to the terms and conditions of licenses granted to us by others.

We may enter into license agreements in the future with others to advance our research or allow commercialization of OP-1250 or any future product candidates we may develop. These and other licenses may not provide

exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in our licenses.

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

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business, including the payment of all applicable fees for patents covering our product candidates. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected. Further, we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control the prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by the actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Our licensors may have relied on third party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may need to obtain additional licenses from existing licensors and others to advance our research or allow commercialization of product candidates we develop. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could significantly harm our business, financial condition, results of operations and prospects significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to

third parties, which could be significant. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

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

Disputes may arise between us and our past, current or future licensors regarding intellectual property subject to a license agreement, including:

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

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could significantly harm our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could significantly harm our business, financial condition and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could significantly harm our competitive position, business, financial condition and prospects.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

We may develop, acquire, or license intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or

grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects.

Risks related to our dependence on third parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize OP-1250 or future product candidates we may develop and our business, financial condition, results of operations and prospects could be significantly harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our nonclinical studies and clinical trials and to monitor and manage data for our ongoing nonclinical and clinical programs. We rely on these parties for execution of our nonclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for OP-1250 in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to OP-1250 and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of OP-1250, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully

commercialize OP-1250. As a result, our results of operations and the commercial prospects for OP-1250 would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely, and our business, financial condition, results of operations and prospects could be significantly harmed.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

The COVID-19 pandemic and government measures taken in response have also had a significant impact on our CROs, and we expect that they will face further disruption which may affect our ability to initiate and complete our nonclinical studies and clinical trials.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. There can be no assurance that we will not encounter challenges or delays with CROs in the future or that these delays or challenges will not significantly harm our business, financial condition, results of operations and prospects.

We contract with third parties for the manufacture of OP-1250 for nonclinical studies and our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of OP-1250 or other drugs necessary for the development or commercialization of OP-1250 or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of OP-1250 for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of OP-1250 for nonclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements for OP-1250. Furthermore, the raw materials for OP-1250 are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of OP-1250 for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of OP-1250 in the future will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects.

We expect to continue to rely on third-party manufacturers for the commercial supply of OP-1250, if we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture OP-1250 according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over OP-1250 or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- disruptions resulting from the impact of public health pandemics or epidemics (including, for example, the ongoing COVID-19 pandemic;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;

- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture OP-1250 according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of OP-1250, or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market OP-1250, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of OP-1250 or other drugs necessary for the development or commercialization of OP-1250 and significantly harm our business, financial condition, results of operations and prospects.

Furthermore, if the third-party providers of therapies or therapies in development used in combination with OP-1250 are unable to produce sufficient quantities for clinical trials or for commercialization of OP-1250, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would significantly harm our business, financial condition, results of operations and prospects. For example, for our planned Phase 1b clinical trial of OP-1250 in combination with ribociclib or alpelisib, or the Novartis Study Drugs, in patients with metastatic ER+ breast cancer, we entered into a Clinical Collaboration and Supply Agreement with Novartis Institutes for BioMedical Research, Inc., or Novartis, or the Novartis Agreement. Under the terms of the Novartis Agreement, Novartis is providing ribociclib (Kisqali®) and alpelisib (Piqray®) for the clinical trial. If Novartis is unable to timely manufacture or provide ribociclib or alpelisib, or if the Novartis Agreement terminates and we are unable to obtain ribociclib or alpelisib on the current terms, our planned Phase 1b clinical trial may be delayed and the cost to us to conduct this trial may significantly increase, which would significantly harm our business, financial condition, results of operations and prospects. For a description of the Novartis Agreement, see the section titled “Business — Clinical Trial Collaboration and Supply Agreement with Novartis.”

Our current and anticipated future dependence upon others for the manufacture of OP-1250 or other drugs necessary for the development or commercialization of OP-1250 may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of OP-1250 for clinical trials or our product for patients, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and

potency. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide nonclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and significantly harm our business, financial condition, results of operations and prospects. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would significantly harm our business, financial condition, results of operations and prospects.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

We have entered into collaborations with third parties for the development and commercialization of OP-1250. If those collaborations are not successful, we may not be able to capitalize on the market potential of OP-1250.

We have third-party collaborators for the development and commercialization of OP-1250. Our likely collaborators for any future collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

We have, and will likely continue to have, limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of OP-1250. Our ability to generate revenues

from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving OP-1250 could pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of OP-1250 or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with OP-1250 if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of OP-1250 or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

If we decide to establish collaborations in the future, but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of OP-1250 or any future product candidates we may develop will require substantial additional cash to fund expenses. We may continue to seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

If we seek collaborations in the future, we will face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate,

the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for OP-1250 or any future product candidates we may develop. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into additional collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop OP-1250 or any future product candidates we may develop or bring them to market and generate product revenue.

Risks related to this offering and ownership of our common stock

There has been no prior public market for our common stock. We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be, and as a result, it may be difficult for you to sell your shares of our common stock.

Prior to this offering, no public market for shares of our common stock existed and an active trading market for our common stock may never develop or be sustained following this offering. We determined the initial public offering price for our common stock through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of common stock as consideration.

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock following this offering is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology 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. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this prospectus, these factors include:

- the timing and results of nonclinical studies and clinical trials of OP-1250 or any future product candidates we may develop or those of our competitors;

- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our product candidate or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions.

In addition, the trading prices for common stock of other biopharmaceutical companies have been highly volatile as a result of factors unrelated to the specific company or its technology, as well as due to the COVID-19 pandemic. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business, nonclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. We do not currently have and may never obtain research coverage by securities or industry analysts. If no or few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

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:

- timing and variations in the level of expense related to the ongoing development of OP-1250 or future development programs;
- timing and status of enrollment for our clinical trials;
- impacts from the COVID-19 pandemic on us or third parties with which we engage;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding 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;
- if OP-1250 or any future product candidate we may develop receive regulatory approval, the timing and terms of such approval and market acceptance and demand for such product candidates;
- the timing and cost to establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with current or future collaborators;
- regulatory developments affecting OP-1250 or any future product candidate we may develop or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below 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.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 81% of our voting stock and, upon the closing of this offering, that same group will beneficially own approximately 58.8% of our outstanding voting stock (based on the initial public offering price of $19.00 per share, and assuming no exercise of the underwriters' option to purchase additional shares) and without giving effect to any purchases that certain of these holders may make through our directed share program or otherwise in this offering. Therefore, even after this offering these stockholders will be able to significantly influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control 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 that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

If you purchase shares of our common stock in our initial public offering, you will experience substantial and immediate dilution.

The initial public offering price is substantially higher than the net tangible book value per share of our outstanding common stock immediately following the closing of this offering. Based on the initial public offering price of $19.00 per share, if you purchase shares of common stock in this offering, you will experience substantial and immediate dilution in the pro forma as adjusted net tangible book value per share of $10.78 per share as of September 30, 2020. That is because the price that you pay will be substantially greater than the pro forma net tangible book value per share of the common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares of our capital stock. You will experience additional dilution when those holding stock options or warrants exercise their right to purchase common stock under our equity incentive plans or when we otherwise issue additional shares of common stock. See the section titled “Dilution.”

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

Our common stock price could decline as a result of sales of a large number of shares of common stock after this offering or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

Upon the closing of this offering, 38,519,738 shares of common stock (including (i) 23,765,075 shares issuable upon the conversion of all outstanding shares of our convertible preferred stock as of September 30, 2020 and (ii) 895,391 shares of unvested restricted common stock subject to repurchase as of such date) will be outstanding (40,169,738 shares if the underwriters exercise their option to purchase additional shares from us in full), based on the number of shares outstanding as of September 30, 2020.

All shares of common stock expected to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, unless held by our “affiliates” as defined in Rule 144 under the Securities Act. The resale of the remaining 23,765,075 shares, or 61.7% of our outstanding shares of common stock following this offering, assuming no exercise of the underwriters’ option to purchase additional shares, is currently prohibited or otherwise restricted as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with this offering. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning 181 days after the date of this prospectus. The representatives of the underwriters may release some or all of the shares of common stock subject to lock-up agreements at any time in their sole discretion and without notice, which would allow for earlier sales of shares in the public market. Shares issued upon the exercise of stock options and warrants outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements and/or lock-up agreements, as well as Rules 144 and 701 under the Securities Act. For more information, see the section titled “Shares Eligible for Future Sale.”

Upon the closing of this offering, the holders of approximately 23,765,075 shares of common stock, or 61.7% of our outstanding shares following this offering, assuming no exercise of the underwriters’ option to purchase additional shares, will have rights, subject to certain conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. We also intend to register the offer and sale of all shares of common stock that we may issue under our equity compensation plans. Once we register the offer and sale of shares for the holders of registration rights and shares that may be issued under our equity incentive plans, these shares will be able to be sold in the public market upon issuance, subject to applicable securities laws and the lock-up agreements described under “Underwriters.”

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to OP-1250 or future product candidates we may develop on unfavorable terms to us.

We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to OP-1250 or future product candidates we may develop, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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 of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in this prospectus and 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 earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

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 intend to take advantage of the extended

transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

The requirements of being a public company may strain our resources, result in more litigation and divert management's attention.

As a public company, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are 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. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial condition, results of operations and prospects may be significantly harmed.

These rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in this prospectus and in future filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business, financial condition, results of operations and prospects.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may significantly harm our business.

As a public company, we will be required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and

determine the effectiveness of our internal control over financial reporting. 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 financial statements will not be prevented or detected on a timely basis.

To date, we have had limited financial and accounting personnel to fully execute our accounting processes and address our internal control over financial reporting. During 2020, in connection with the preparation of our financial statements as of and for the years ended December 31, 2019 and 2018, we identified material weaknesses in our control over financial reporting.

First, we did not design and therefore did not have an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately. This material weakness contributed to an additional material weakness in that we did not design and therefore did not have formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations and journal entries.

While these materials weaknesses did not result in a misstatement for the years ended December 31, 2019 and 2018, each of the above material weaknesses could have resulted in a misstatement of the aforementioned account balances or disclosures that would have resulted in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

Since June 2020 and in order to remediate the material weakness in our internal control over financial reporting and address the material weakness in our accounting processes, we have been establishing, and continue to establish, more robust accounting policies and procedures, reviews on the adoption of new accounting positions and the need for financial statement disclosures, and selection and engagement of consultants to assist us in determining positions and evaluating new accounting policies.

We began implementing and we plan to continue to implement the following steps to address the internal control deficiencies that contributed to the material weaknesses, including the following:

- hiring of additional finance and accounting personnel with prior experience working for finance departments of public companies and technical accounting experience, supplemented by third-party resources;
- documenting and formally assessing our accounting and financial reporting policies and procedures; and
- assessing significant accounting transactions and other technical accounting and financial reporting issues, preparing accounting memoranda addressing these issues and maintaining these memoranda in our corporate records.

While we believe that these efforts will improve our internal control over financial reporting, the implementation of these measures is ongoing and will require validation and testing of the design and operating effectiveness of internal controls over a sustained period of financial reporting cycles. We cannot reasonably estimate when these remediation measures will be completed nor can we assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal controls over financial reporting. Furthermore, we may not have identified all material weaknesses, and our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Accordingly, there continues to be a reasonable possibility that these deficiencies or others could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis.

If we continue to fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement

required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We could be an emerging growth company for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.

To the extent our existing stockholders who are our affiliates and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and controlling stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

Our management team has broad discretion to use the net proceeds from this offering and its investment of these proceeds may not yield a favorable return. They may invest the net proceeds from this offering in ways with which investors disagree.

We intend to use a portion of the net proceeds from this offering to advance and expand our clinical and nonclinical development programs and for working capital and for other general corporate purposes, which may include the hiring of additional personnel, capital expenditures and the costs of operating as a public company. See the section titled "Use of Proceeds." However, within the scope of our plan, and in light of the various risks to our business, including those discussed in this "Risk Factors" section and elsewhere in this prospectus, our management will have broad discretion over the use of net proceeds from this offering, and could spend the net proceeds in ways our stockholders may not agree with or that do not yield a favorable return, if at all. If we do not invest or apply the net proceeds from this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation and shareholder derivative actions. We may be the target of these types of litigation and claims in the future. These claims and litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business, financial condition, results of operations and prospects.

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

We have never declared or paid any cash dividends on our equity securities. 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 any appreciation in the value of our common stock, which is not certain.

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

We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 ⅔% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our amended and restated certificate of incorporations or amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could

delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine or otherwise related to our internal affairs.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

This exclusive-forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business, financial condition, results of operations and prospects.

Special note regarding forward-looking statements

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

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “would,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “believe,” “estimate,” “predict,” “potential,” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- our financial performance;
- the sufficiency of our existing cash to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- the scope, progress, results and costs of developing OP-1250 or any other product candidates we may develop, and conducting nonclinical studies and clinical trials, including our OP-1250 Phase 1/2 clinical trial;
- the timing and costs involved in obtaining and maintaining regulatory approval of OP-1250 or any other product candidates we may develop, and the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations for our product candidates for various diseases;
- our plans relating to commercializing OP-1250 and any other product candidates we may develop, if approved, including the geographic areas of focus and our ability to grow a sales team;
- the impact of the COVID-19 pandemic on our business and operations, including enrollment in our clinical trial;
- the implementation of our strategic plans for our business and OP-1250 or any other product candidates we may develop;
- the size of the market opportunity for OP-1250 or any other product candidates we may develop in each of the diseases we target;
- our reliance on third parties to conduct nonclinical research activities, and for the manufacture of OP-1250 and any other product candidates we may develop;
- the beneficial characteristics, safety, efficacy and therapeutic effects of OP-1250 and any other product candidates we may develop;
- our estimates of the number of patients in the United States who suffer from the diseases we target and the number of subjects that will enroll in our clinical trials;
- the progress and focus of our current and future clinical trials, and the reporting of data from those trials;
- our ability to advance product candidates into and successfully complete clinical trials;
- the ability of our clinical trials to demonstrate the safety and efficacy of OP-1250 and any other product candidates we may develop, and other positive results;
- the success of competing therapies that are or may become available;
- developments relating to our competitors and our industry, including competing product candidates and therapies;

- our plans relating to the further development and manufacturing of OP-1250 and any other product candidates we may develop, including additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our potential and ability to successfully manufacture and supply OP-1250 and any other product candidates we may develop for clinical trials and for commercial use, if approved;
- the rate and degree of market acceptance of OP-1250 and any other product candidates we may develop, as well as the pricing and reimbursement of OP-1250 and any other product candidates we may develop, if approved;
- our continued reliance on third parties to conduct additional clinical trials of OP-1250 and any other product candidates we may develop, and for the manufacture of our product candidates;
- our plans and ability to obtain and protect intellectual property rights;
- the scope of protection we are able to establish and maintain for intellectual property rights, including OP-1250 and any other product candidates we may develop;
- our ability to retain the continued service of our key personnel and to identify, hire, and then retain additional qualified personnel;
- our expectations regarding the impact of the COVID-19 pandemic on our business and operations, including clinical trials, manufacturing suppliers, collaborators, use of CROs and employees;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing cash and cash equivalents and the proceeds from this offering.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events or otherwise.

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

Market, industry and other data

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

Use of proceeds

We estimate that we will receive net proceeds from this offering of approximately $191.1 million (or approximately $220.3 million if the underwriters' option to purchase 1,650,000 additional shares of our common stock is exercised in full) based on the initial public offering price of $19.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, establish a public market for our common stock and facilitate our future access to the public capital markets.

As of September 30, 2020, we had cash and cash equivalents of $127.8 million. We intend to use the net proceeds we receive from this offering together with our existing cash and cash equivalents, as follows:

- approximately $40.0 million to $60.0 million to complete our ongoing Phase 1/2 monotherapy clinical trial;
- approximately $10.0 million to $20.0 million to advance OP-1250 through our planned Phase 1b combination trials with CDK4/6i and PI3Kα; and
- the remainder for other ongoing research and development activities, and for other general corporate purposes, including working capital, operating expenses and capital expenditures.

We may also use a portion of the remaining net proceeds and our existing cash and cash equivalents to in-license, acquire, or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

We believe, based on our current operating plan, that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations for at least the next 24 months. In particular, we expect that the net proceeds from this offering will allow us to complete our ongoing Phase 1/2 dose escalation and expansion clinical trial of OP-1250 for the treatment of recurrent, locally advanced or metastatic ER+, human epidermal growth factor receptor 2-negative, or HER2-, breast cancer and begin to study OP-1250 in combination with other targeted breast cancer therapies. However, our expected use of proceeds from this offering described above represents our current intentions based on our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds to be received upon the closing of this offering or the actual amounts that we will spend on the uses set forth above. The net proceeds from this offering, together with our cash and cash equivalents, will not be sufficient for us to fund OP-1250 through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of OP-1250 and any future product candidates we may develop.

The amounts and timing of our actual expenditures will depend on numerous factors, including the time and cost necessary to conduct our planned clinical trials, the results of our planned clinical trials and other factors described in the section titled "Risk Factors" in this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes. We will have broad discretion over how to use the net proceeds to us from this offering. We intend to invest the net proceeds to us from the offering that are not used as described above in short-term, investment-grade, interest-bearing instruments.

Dividend policy

We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws, and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. In addition, our ability to pay cash dividends on our capital stock in the future may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

Capitalization

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2020:

- on an actual basis;
- on a pro forma basis, giving effect to the (i) automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 23,765,075 shares of our common stock which will occur upon the closing of this offering, and the related reclassification of the carrying value of our convertible preferred stock to permanent equity upon the closing of this offering, and (ii) filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately after the closing of this offering; and
- on a pro forma as adjusted basis, giving effect to the (i) pro forma adjustments set forth above and (ii) our receipt of net proceeds from the sale of 11,000,000 shares of common stock in this offering at the initial public offering price of $19.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with the sections titled “Selected Financial Data,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Description of Capital Stock” and our financial statements and related notes included elsewhere in this prospectus.

	As of September 30, 2020		
(in thousands, except share and per share amounts)	Actual	Pro forma	Pro forma as adjusted
		(unaudited)	
Cash and cash equivalents	$127,824	$ 127,824	$ 319,808
Convertible preferred stock, $0.0001 par value per share; 66,897,006 shares authorized, 23,765,075 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	$148,373	$ —	—
Stockholders’ equity (deficit):			
Common stock, $0.0001 par value per share; 88,000,000 shares authorized, 2,859,272 shares issued and outstanding, excluding 895,391 shares subject to repurchase, actual; 490,000,000 shares authorized, 26,624,347 shares issued and outstanding, excluding 895,391 shares subject to repurchase, pro forma; 490,000,000 shares authorized, 37,624,347 shares issued and outstanding, excluding 895,391 shares subject to repurchase, pro forma as adjusted	1	3	4
Preferred stock, $0.0001 par value per share; no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Additional paid-in capital	—	148,370	339,464
Accumulated deficit	(22,964)	(22,963)	(22,963)
Total stockholders’ equity (deficit)	(22,963)	125,410	316,505
Total capitalization	$125,410	$ 125,410	$ 316,505

The number of shares of our common stock to be issued and outstanding, pro forma and pro forma as adjusted in the table above is based on 26,624,347 shares of common stock outstanding as of September 30, 2020 (including 23,765,075 shares issuable upon the conversion of all outstanding shares of our convertible preferred stock of September 30, 2020), and excludes:

- 895,391 shares of unvested restricted common stock subject to repurchase as of September 30, 2020;

- 2,505,811 shares of our common stock issuable upon the exercise of outstanding stock options as of September 30, 2020, with a weighted-average exercise price of $4.14 per share;
- 2,152,080 shares of our common stock reserved for future issuance under our 2020 Equity Incentive Plan, or 2020 Plan, which became effective once the registration statement of which this prospectus forms a part was declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2020 Plan and any shares underlying outstanding stock awards granted under our 2014 Stock Plan, or 2014 Plan, that expire or are repurchased, forfeited, cancelled or withheld, as more fully described in the section titled “Executive Compensation—Equity Benefit Plans” (of which options to purchase an aggregate of 2,144,891 shares of our common stock were granted to certain of our non-employee directors, executive officers and other employees at the time of effectiveness of the 2020 Plan with an exercise price equal to the initial public offering price per share); and
- 430,416 shares of our common stock reserved for issuance under our 2020 Employee Stock Purchase Plan, or ESPP, which became effective once the registration statement of which this prospectus forms a part was declared effective, and any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP.

Dilution

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the initial public offering price per share of common stock and the pro forma as adjusted net tangible book value per share immediately after this offering.

As of September 30, 2020, we had a historical net tangible book (deficit) of $(24.4) million, or $(8.55) per share of common stock based on the 2,859,272 shares of common stock outstanding as of such date, excluding 895,391 shares subject to repurchase as of such date. Our historical net tangible book value per share represents total tangible assets less our deferred initial public offering costs, liabilities and convertible preferred stock, which is not included within stockholders' deficit, divided by the number of shares of common stock outstanding as of September 30, 2020, excluding 895,391 shares subject to repurchase as of such date.

Our pro forma net tangible book value as of September 30, 2020 was $123.9 million, or $4.50 per share. Pro forma net tangible book value per share represents the amount of our total tangible assets less our total liabilities, divided by 27,519,738 shares of common stock outstanding as of such date, after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 23,765,075 shares of our common stock and the related reclassification of the carrying value of our convertible preferred stock to permanent equity upon the closing of this offering, (ii) the inclusion of 895,391 shares of unvested restricted common stock subject to repurchase as of such date, and (iii) the filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately after the closing of this offering.

After giving effect to the sale by us of 11,000,000 shares of common stock in this offering at the initial public offering price of $19.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2020 would have been $316.5 million, or $8.22 per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value of $3.72 per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of $10.78 per share to investors purchasing common stock in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash paid by an investor for a share of common stock in this offering. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$ 19.00
Historical net tangible book (deficit) per share as of September 30, 2020	$ (8.55)	
Pro forma increase in historical net tangible book value per share attributable to the pro forma transactions described in the preceding paragraphs	13.05	
Pro forma net tangible book value per share as of September 30, 2020	4.50	
Increase in pro forma as adjusted net tangible book value per share attributable to investors purchasing shares in this offering	3.72	
Pro forma as adjusted net tangible book value per share after this offering		8.22
Dilution in pro forma as adjusted net tangible book value per share to investors purchasing shares in this offering		$ 10.78

If the underwriters exercise their option to purchase additional shares of common stock in full, the pro forma net tangible book value per share, as adjusted to give effect to this offering, would be $8.61 per share, and the dilution in pro forma net tangible book value per share to investors in this offering would be $10.39 per share.

The following table summarizes, on the pro forma as adjusted basis described above, as of September 30, 2020, the number of shares of common stock purchased from us, the total consideration paid, or to be paid, and the weighted-average price per share paid, or to be paid, by existing stockholders and by investors purchasing shares in this offering at the initial public offering price of $19.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration[1]		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders[2]	27,519,738	71.4%	$153,123,673[1]	42.3%	$ 5.55
New public investors	11,000,000	28.6%	209,000,000	57.7%	$ 19.00
Total	38,519,738	100.0%	$362,123,673	100.0%	

(1) Includes non-cash consideration of $9,067,660.

(2) The presentation in this table regarding ownership by existing stockholders does not give effect to any purchases that existing stockholders may make through our directed share program or otherwise purchase in this offering.

The table above assumes no exercise of the underwriters' option to purchase 1,650,000 additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to 68.5% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by investors purchasing shares of common stock in the offering would be increased to 31.5% of the total number of shares outstanding after this offering.

The foregoing discussion and tables above (other than the historical net tangible book value calculation) are based on 27,519,738 shares of common stock outstanding as of September 30, 2020 (including (i) 23,765,075 shares issuable upon the conversion of all outstanding shares of our convertible preferred stock as of September 30, 2020 and (ii) 895,391 shares of unvested restricted common stock subject to repurchase as of such date), and excludes:

- 2,505,811 shares of our common stock issuable upon the exercise of outstanding stock options as of September 30, 2020, with a weighted-average exercise price of $4.14 per share;
- 2,152,080 shares of our common stock reserved for future issuance under our 2020 Plan, which became effective once the registration statement of which this prospectus forms a part was declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2020 Plan and any shares underlying outstanding stock awards granted under our 2014 Plan that expire or are repurchased, forfeited, cancelled or withheld, as more fully described in the section titled "Executive Compensation—Equity Benefit Plans" (of which options to purchase an aggregate of 2,144,891 shares of our common stock were granted to certain of our non-employee directors, executive officers and other employees at the time of effectiveness of the 2020 Plan with an exercise price equal to the initial public offering price per share); and
- 430,416 shares of our common stock reserved for issuance under our ESPP, which became effective once the registration statement of which this prospectus forms a part was declared effective, and any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP.

To the extent that any outstanding options are exercised or new options are issued under our stock-based compensation plans, or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering.

Selected financial data

The following tables set forth our selected financial data for the periods and as of the dates indicated. The following selected statements of operations data for the years ended December 31, 2018 and 2019, and our selected balance sheet data as of December 31, 2018 and 2019, have been derived from our audited financial statements included elsewhere in this prospectus. The following selected statements of operations data for the nine months ended September 30, 2019 and 2020 and the selected balance sheet data as of September 30, 2020 have been derived from our unaudited interim condensed financial statements included elsewhere in this prospectus. The unaudited interim condensed financial statements were prepared on a basis consistent with our audited financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future and our interim results are not necessarily indicative of our expected results for the year ending December 31, 2020. You should read the following selected financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus. The selected financial data included in this section are not intended to replace the financial statements and are qualified in their entirety by our financial statements and the related notes included elsewhere in this prospectus.

	Year ended December 31,		Nine months ended September 30,	
(in thousands, except share and per share data)	**2018**	**2019**	**2019**	**2020**
			(unaudited)	
Operating expenses:				
Research and development	$ 1,693	$ 3,920	$ 3,010	$ 7,415
General and administrative	386	403	296	3,982
Total operating expenses	2,079	4,323	3,306	11,397
Loss from operations	(2,079)	(4,323)	(3,306)	(11,397)
Other (expense) income:				
Interest income	4	7	7	59
Interest (expense)	(28)	—		(653)
Other income	—	—	—	1
Loss on extinguishment of convertible notes	(63)	—	—	—
Loss on remeasurement of convertible notes	(31)	—	—	—
Total other (expense) income, net	(118)	7	7	(593)
Net loss and comprehensive loss[(1)]	(2,197)	(4,316)	(3,299)	(11,990)
Repurchase and retirement of Series A and Series A-1 convertible preferred stock	—	—	—	(1,869)
Net loss attributable to common stockholders	$ (2,197)	$ (4,316)	$ (3,299)	$ (13,859)
Net loss per share attributable to common stockholders, basic and diluted[(1)]	$ (0.87)	$ (1.66)	$ (1.27)	$ (5.29)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted[(1)]	2,522,577	2,593,316	2,593,316	2,617,543
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[(1)]		$ (0.60)		$ (0.98)
Weighted-average shares used to compute pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[(1)]		7,221,531		14,098,571

(1) See Note 11 to our financial statements included elsewhere in this prospectus for a description of how we compute basic and diluted net loss per share attributable to common stockholders and pro forma basic and diluted net loss per share attributable to common stockholders.

(in thousands)	As of December 31, 2018	2019	As of September 30, 2020 (unaudited)
Balance Sheet Data:			
Cash and cash equivalents	$ 3,149	$ 68	$ 127,824
Working capital[(1)]	3,041	(1,275)	123,814
Total assets	3,271	132	130,683
Total liabilities	201	1,378	5,273
Convertible preferred stock	9,348	9,348	148,373
Accumulated deficit	(6,446)	(10,762)	(22,964)
Total stockholders' deficit	(6,278)	(10,594)	(22,963)

(1) We define working capital as current assets less current liabilities. See our financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

Management's discussion and analysis of financial condition and results of operations

The following discussion should be read in conjunction with the section titled "Selected Financial Data" and our financial statements and related notes thereto included elsewhere in this prospectus. In addition to historical information, this discussion contains forward-looking statements that involve risks, uncertainties and assumptions that could cause actual results to differ materially from management's expectations. Factors that could cause such differences are discussed in the sections titled "Special Note Regarding Forward-Looking Statements" and "Risk Factors." We are not undertaking any obligation to update any forward-looking statements or other statements we may make in the following discussion or elsewhere in this document even though these statements may be affected by events or circumstances occurring after the forward-looking statements or other statements were made. Therefore, no reader of this document should rely on these statements being current as of any time other than the time at which this document is declared effective by the SEC.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of next generation targeted therapies for women's cancers. Our team has spent the past decade characterizing the structure and function of the ER, a key driver of breast cancer in approximately 75% of patients, in order to develop more potent, oral therapies that completely inactivate this signaling pathway. Our wholly-owned, lead product candidate, OP-1250, is a novel oral therapy with combined activity as both a CERAN and a SERD, which we believe will drive deeper, more durable responses than existing therapies. OP-1250, both as a monotherapy and in combination with inhibitors of CDK4/6 demonstrated robust tumor shrinkage in several xenograft models, including a breast cancer brain metastasis model. In August 2020, we initiated an ongoing Phase 1/2 dose escalation and expansion trial evaluating OP-1250 for the treatment of recurrent, locally advanced or metastatic ER+, HER2- breast cancer, and expect to report initial data from this trial in the second half of 2021. We own worldwide development and commercialization rights to OP-1250. As summarized in the figure below, our plan is to develop OP-1250 in a number of ER+ breast cancer indications, both as a monotherapy and in combination with approved targeted therapies that have shown improved outcomes with other endocrine therapies. We believe OP-1250's oral formulation and dual mechanism of action directly address the limitations of current endocrine therapies, such as fulvestrant and tamoxifen, and position OP-1250 as a potential endocrine therapy of choice for the treatment of ER+ breast cancers. Our goal is to transform the standard of care for women living with cancers by developing more effective therapies that apply our deep understanding and collective expertise in endocrine-driven cancers, nuclear receptor activities and mechanisms of acquired resistance.

Since our inception, we have devoted substantially all of our resources to organizing and staffing our company, research and development activities, business planning, raising capital, establishing and maintaining our intellectual property portfolio, conducting nonclinical studies and clinical trials and providing general and administrative support for these operations.

We do not have any product candidates approved for commercial sale, and we have not generated any revenue from product sales. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful development and eventual commercialization of one or more of our product candidates which we expect, if it ever occurs, will take a number of years. We also do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for nonclinical and clinical testing, as well as for commercial manufacturing if any of our product candidates obtain marketing approval. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

To date, we have funded our operations primarily through proceeds from the sale of shares of our common stock, convertible preferred stock and convertible promissory notes. As of December 31, 2019, we had $0.1 million in

cash and cash equivalents. In January 2020, we received proceeds of $3.0 million from the issuance of convertible promissory notes, or the 2020 Notes. From March 2020 through June 2020, we issued 10,801,277 shares of our Series B convertible preferred stock at a price of $4.712 per share for cash proceeds of $50.9 million, and 638,270 shares of our Series B convertible preferred stock upon conversion of the 2020 Notes (including accrued interest). In September 2020, we issued 7,904,135 shares of our Series C convertible preferred stock at a price of $11.063 per share for cash proceeds of $87.4 million. Through September 30, 2020, we had received aggregate gross proceeds of $151.0 million from sales of our common stock, convertible preferred stock and issuance of convertible promissory notes since inception. As of September 30, 2020, we had cash and cash equivalents of $127.8 million. Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our planned operating expenses and capital expenditure requirements for at least the next 24 months.

We have incurred significant operating losses since the commencement of our operations. Our net losses were $2.2 million, $4.3 million and $12.0 million for the years ended December 31, 2018 and 2019 and the nine months ended September 30, 2020, respectively, and we expect to incur significant and increasing losses for the foreseeable future as we continue to advance our product candidate, and as we transition to operating as a public company. Our net losses may fluctuate significantly from period to period, depending on the timing of expenditures on our research and development activities. As of September 30, 2020, we had an accumulated deficit of $23.0 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and other current liabilities.

We expect to continue to incur net operating losses for at least the next several years, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. We expect our expenses and capital requirements will increase significantly in connection with our ongoing activities as we:

- continue our ongoing and planned research and development of our lead product candidate OP-1250 for the treatment of ER+ positive breast cancer;
- initiate nonclinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know how;
- acquire or in-license other product candidates and technologies;
- attract, hire and retain additional clinical, scientific, quality control, and manufacturing management and administrative personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- expand our operations in the United States and to other geographies; and
- incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

We also expect to increase the size of our administrative function to support the growth of our business. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We will require substantial additional funding to develop our product candidates and support our continuing operations. Until such time that we can generate significant revenue from product sales or other sources, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, which could include income from collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic and otherwise. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to have to delay, reduce or eliminate our product development or future commercialization efforts. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts. We cannot provide assurance that we will ever be profitable or generate positive cash flow from operating activities.

The COVID-19 pandemic continues to rapidly evolve. As a result of the COVID-19 pandemic, we experienced some delays in setting up our current Phase 1/2 clinical trial and in clinical site initiation, including delays in recruiting clinical site investigators and clinical site staff, which we may experience again in the future. The extent of the impact of the COVID-19 pandemic on our business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our development activities, planned clinical trial enrollment, future trial sites, CROs, third-party manufacturers, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and with our employees working remotely. We will continue to actively monitor the rapidly evolving situation related to the COVID-19 pandemic and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. At this point, the extent to which the COVID-19 pandemic may affect our business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain.

Components of our results of operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products for the foreseeable future.

Operating expenses

Research and development

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal expenses incurred in connection with the discovery and development of our product candidates. To date, our research and development expenses have related primarily to discovery efforts and nonclinical and clinical development of our product candidate OP-1250. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

External expenses include:

- expenses incurred in connection with the discovery and nonclinical development of our product candidates, including under agreements with third parties, such as consultants and CROs;
- the cost of manufacturing products for use in our nonclinical studies and clinical trials, including payments to CMOs and consultants;
- the costs of funding research performed by third parties;
- costs of purchasing lab supplies and non-capital equipment used in designing, developing and manufacturing nonclinical study and clinical trial materials;
- costs associated with consultants for chemistry, manufacturing and controls development, regulatory, statistics and other services;
- expenses related to regulatory activities, including filing fees paid to regulatory agencies; and
- facility costs including rent, depreciation and maintenance expenses.

Internal expenses include employee and personnel-related costs and expenses, including salaries, benefits and stock-based compensation expense for employees and personnel engaged in research and development functions.

We expense research and development expenses in the periods in which they are incurred. Costs for certain activities, such as manufacturing and nonclinical studies and clinical trials, are generally recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and collaborators.

We typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by product candidate or nonclinical program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or nonclinical programs.

Research and development expenses to advance the development of our product candidate and nonclinical program were $1.7 million and $3.9 million for the years ended December 31, 2018 and 2019, respectively, and $3.0 million and $7.4 million for the nine months ended September 30, 2019 and 2020, respectively.

We expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we advance OP-1250 or any other future product candidates we may develop into and through nonclinical studies and clinical trials and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for OP-1250 or any other future product candidates we may develop may be affected by a variety of factors including: the safety and efficacy of our product candidates, early clinical data, investment in our clinical program, the ability of collaborators to successfully develop our licensed product candidates, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for our product candidates. As a result of the uncertainties discussed above, 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 and sale of our OP-1250 or any other future product candidates we may develop. Clinical and nonclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future nonclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. In addition, we cannot forecast whether OP-1250 or any other future product candidates we may develop may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We are also unable to predict when, if ever, we will generate revenue from our product candidates to offset these expenses. Our expenditures on current and future nonclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. The

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

- the timing and progress of nonclinical and clinical development activities;
- the number and scope of nonclinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- establishing an appropriate safety profile with investigational new drug-enabling toxicology studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- our ability to establish licensing or collaboration arrangements;
- the performance of our future collaborators, if any;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- development and timely delivery of commercial-grade product formulations that can be used in our planned clinical trials and for commercial launch;
- commercializing the product candidate, if approved, whether alone or in collaboration with others;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidate;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- maintaining a continued acceptable safety profiles of our products following approval; and
- obtaining and retaining key research and development personnel.

Any changes in the outcome of any of these factors could significantly impact the costs, timing and viability associated with the development of our product candidates.

General and administrative

General and administrative expenses consist primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for personnel in executive, finance, accounting, business development, legal, human resource and administrative functions. General and administrative expenses also include corporate facility costs not otherwise included in research and development expenses, depreciation and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance, not otherwise included in research and development expenses, as well as professional fees for legal, patent and consulting services.

We expect that our general and administrative expenses will increase substantially in the foreseeable future as we increase our headcount to support the continued research and development of our programs and the growth of our business. We also anticipate incurring additional expenses associated with operating as a public company, including increased expenses related to audit, legal, regulatory, compliance, director and officer insurance, investor and public relations and tax-related services associated with maintaining compliance with the rules and regulations of the SEC and standards applicable to companies listed on a national securities exchange, additional insurance expenses, investor relations activities and other administrative and professional services.

Total other income (expense), net

Interest income, interest expense and other income

Interest income and interest expense primarily consists of interest income on our cash and cash equivalents. Interest expense primarily consists of interest on our convertible promissory notes, and in the nine months ended September 30, 2020, a non-cash interest charge related to a beneficial conversion feature on a convertible note issued in January 2020. Other income consists of miscellaneous income not related to operating activities.

Loss on extinguishment of convertible notes

Loss on extinguishment of convertible promissory notes consists of the loss recognized from the extinguishment of the unpaid principal and accrued interest on convertible promissory notes issued in 2017. These notes were extinguished in July 2018 and noteholders were issued Series A-1 convertible preferred stock and common stock concurrent with the extinguishment of the notes.

Loss on remeasurement of convertible notes

Loss on remeasurement of convertible promissory notes consists of the loss recognized from the remeasurement of convertible promissory notes issued in 2018. In July 2018, these notes were remeasured to their final fair value, and then settled with the issuance of Series A-1 convertible preferred stock and common stock provided to noteholders.

Results of operations

Comparison of the nine months ended September 30, 2019 and 2020 (unaudited)

The following table summarizes our results of operations for the nine months ended September 30, 2019 and 2020:

	Nine Months Ended September 30,		
	2019	2020	Change
	(unaudited) (in thousands)		
Operating expenses:			
Research and development	$ 3,010	$ 7,415	$ 4,405
General and administrative	296	3,982	3,686
Total operating expenses	3,306	11,397	8,091
Loss from operations	(3,306)	(11,397)	(8,091)
Other (expense) income:			
Interest income	7	59	52
Interest expense	—	(653)	(653)
Other income	—	1	1
Total other (expense) income, net	7	(593)	(600)
Net loss and comprehensive loss	$(3,299)	$ (11,990)	$(8,691)

Research and development expenses

Research and development expenses for the nine months ended September 30, 2019 were $3.0 million, compared to $7.4 million for the nine months ended September 30, 2020. The increase of $4.4 million was primarily due to increased spending for nonclinical research of OP-1250, including the hiring of new employees and increased spending with external vendors on research and development services.

General and administrative expenses

General and administrative expenses for the nine months ended September 30, 2019 were $0.3 million compared to $4.0 million for the nine months ended September 30, 2020. The increase of $3.7 million was primarily due to increased salary expense associated with the expanded executive team and fees paid to outside consultants in connection with our preparation to operate as a public company.

Other (expense) income, net

Other (expense) income, net for the nine months ended September 30, 2019 was insignificant, compared to $(0.6) million during the nine months ended September 30, 2020. The change was primarily due to the $(0.7) million of interest expense incurred in the nine months ended September 30, 2020. The interest expense primarily consisted of a non-cash interest charge incurred in connection with convertible notes issued in January 2020.

Comparison of the years ended December 31, 2018 and 2019

The following table summarizes our results of operations for the years ended December 31, 2018 and 2019:

	Years ended December 31,		
	2018	2019	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 1,693	$ 3,920	$ 2,227
General and administrative	386	403	17
Total operating expenses	2,079	4,323	2,244
Loss from operations	(2,079)	(4,323)	(2,244)
Other (expense) income:			
Interest income	4	7	3
Interest expense	(28)	—	28
Loss on extinguishment of convertible notes	(63)	—	63
Loss on remeasurement of convertible notes	(31)	—	31
Total other (expense) income, net	(118)	7	125
Net loss and comprehensive loss	$(2,197)	$(4,316)	$(2,119)

Research and development expenses

Research and development expenses for the year ended December 31, 2018 were $1.7 million, compared to $3.9 million for the year ended December 31, 2019. The increase of $2.2 million was primarily due to the nonclinical research of OP-1250 and included a $0.7 million increase in lab services costs and $1.5 million increase in third-party research and development fees.

General and administrative expenses

General and administrative expenses remained relatively unchanged year over year and were $0.4 million for the years ended December 31, 2018 and 2019, respectively.

Other (expense) income, net

Other (expense) income, net for the year ended December 31, 2018 was less than $(0.1) million, compared to less than $0.1 million during the year ended December 31, 2019. The change was primarily due to the $0.1 million loss on extinguishment and remeasurement of convertible promissory notes in 2018.

Liquidity and capital resources

Sources of liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. Our net losses were $2.2 million and $4.3 million for the years ended December 31, 2018 and 2019, respectively and $3.3 million and $12.0 million for the nine months ended September 30, 2019 and 2020, respectively. As of September 30, 2020, we had $127.8 million in cash and cash equivalents and an accumulated deficit of $23.0 million. We had no debt outstanding as of September 30, 2020. To date, we have funded our operations primarily through proceeds from the sale of shares of our common stock, convertible preferred stock and convertible promissory notes. In January 2020, we received proceeds of $3.0 million from the issuance of convertible promissory notes, or the 2020 Notes. From March 2020 through June 2020, we issued 10,801,277 shares of our Series B convertible preferred stock at a price of $4.712 per share for cash proceeds of $50.9 million, and 638,270 shares of our Series B convertible preferred stock upon conversion of the 2020 Notes (including accrued interest). In September 2020, we issued 7,904,135 shares of our Series C convertible preferred stock at a price of $11.063 per share for gross proceeds of $87.4 million. Through September 30, 2020, we had received aggregate gross proceeds of $151.0 million from sales of our common stock, convertible preferred stock and issuance of convertible promissory notes since inception.

We expect to incur significant expenses and operating losses for the foreseeable future as we advance the nonclinical and clinical development of OP-1250. We expect that our research and development and general and administrative costs will increase in connection with conducting additional nonclinical studies and clinical trials for our current and future research programs and product candidates, contracting with CMOs to support nonclinical studies and clinical trials, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

Our primary uses of cash are to fund our research and development activities, including with respect to OP-1250 and other nonclinical programs, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations.

Other than our operating lease obligations, we currently have no financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years.

Future funding requirements

To date, we have not generated any revenue from product sales. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if at all, that will occur. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidate. In addition, if we obtain marketing approval for our product candidate, we expect to incur significant commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Furthermore, following the closing of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect our existing cash, together with the net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of product discovery, nonclinical studies and clinical trials;

- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidate;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we enter into;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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

Cash flows

The following table shows a summary of our cash flows for each of the periods presented:

	Year Ended December 31,		Nine Months Ended September 30,	
(in thousands)	**2018**	**2019**	**2019**	**2020**
			(unaudited)	
Net cash used in operating activities	$ (2,176)	$ (3,081)	$(2,233)	$ (10,853)
Net cash used in investing activities	—	—	—	(5)
Net cash provided by financing activities	5,254	—	—	138,614
Net increase (decrease) in cash and cash equivalents	$ 3,078	$ (3,081)	$(2,233)	$127,756

Operating activities

Net cash used in operating activities during the year ended December 31, 2018 consisted primarily of our net loss of $2.2 million. The net loss consisted of $1.7 million of research and development expenses, $0.4 million of general and administrative expenses and $(0.1) million of other (expenses) income, net.

Net cash used in operating activities during the year ended December 31, 2019 consisted primarily of our net loss of $4.3 million, partially offset by an increase in accounts payable of $1.2 million. The net loss primarily consisted of $3.9 million in research and development expenses and $0.4 million in general and administrative expenses. The increase in accounts payable and other current liabilities was due to the timing of the posting of the invoices and the overall increase in research and development expenses in the year ended 2019.

Net cash used in operating activities during the nine months ended September 30, 2019 consisted primarily of our net loss of $3.3 million, partially offset by an increase in accounts payable and other current liabilities of $1.0 million. The net loss consisted primarily of $3.0 million in research and development expenses and $0.3 million in general and administrative expenses. The increase in accounts payable and other current liabilities was due to the timing of the posting of the invoices and the overall increase in research and development expenses in the nine months ended September 30, 2019.

Net cash used in operating activities during the nine months ended September 30, 2020 consisted primarily of our net loss of $12.0 million and cash used in changes in operating assets and liabilities of $0.2 million, partially offset by net non-cash charges of $1.4 million. The changes in operating assets and liabilities consisted primarily of an increase in prepaid expenses and other current assets of $1.3 million and an increase of accounts payable and other current liabilities of $1.1 million. The increase in prepaid expenses and other current assets was driven by an increase in prepaid clinical trial costs. The increase in accounts payable and other liabilities was driven by an increase in costs related to research and development and professional costs incurred in preparation for our planned initial public offering. The non-cash charges primarily consisted of stock compensation of $0.7 million and non-cash interest expense of $0.6 million. The net loss consisted primarily of $7.4 million in research and development expenses and $4.0 million in general and administrative expenses.

Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2020 consisted of nominal purchases of equipment. There were no cash flows from investing activities during the nine months ended September 30, 2019 and years ended December 31, 2019 and 2018.

Financing activities

Net cash provided by financing activities during the year ended December 31, 2018 consisted primarily of $4.9 million in proceeds from the sale and issuance of our Series A-1 convertible preferred stock and $0.3 million in proceeds from the sale and issuance of our convertible promissory notes, net of issuance costs.

There were no cash flows from financing activities during the nine months ended September 30, 2019 or year ended December 31, 2019.

Net cash provided by financing activities during the nine months ended September 30, 2020 consisted primarily of $3.0 million in proceeds from the sale and issuance of our convertible promissory notes, $50.6 million in net proceeds from the sale and issuance of our Series B convertible preferred stock, $87.4 million in net proceeds from the sale and issuance of our Series C convertible preferred stock, $0.6 million of proceeds from the exercise of employee stock options and $0.1 million proceeds from the settlement of non-recourse notes, net of issuance costs. These cash inflows were partially offset by cash outflows of $2.3 million for the repurchase of Series A convertible preferred stock and Series A-1 convertible preferred stock and $0.9 million in payments of offering costs associated with our planned initial public offering.

Contractual obligations and commitments

The following table summarizes our contractual obligations and commitments as of September 30, 2020:

	Payments due by period				
(in thousands)	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Operating leases	$ 2,699	$ 264	$ —	$ —	$2,963

We enter into contracts in the normal course of business with CROs for clinical trials, nonclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Internal control over financial reporting

In the preparation of our financial statements to meet the requirements of this offering, we determined material weaknesses in our internal control over financial reporting existed during 2019 and remained unremediated as of September 30, 2020. See the section titled “Risk Factors —We have identified material weaknesses in our internal control over financial reporting. Although we have already taken a number of steps to remediate, If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.”

Off-balance sheet arrangements

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

Critical accounting policies and significant judgements and estimates

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

While our significant accounting policies are described in more detail in Note 2 to our financial statements elsewhere in this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our audited financial statements.

Stock-Based Compensation

All stock-based compensation cost, including grants of stock options and restricted stock awards issued under our equity incentive plan, is measured at the grant date based on the fair value of the award and is recognized as an expense on a straight-line basis over the requisite service period, which is generally the vesting period. We recognize stock-based compensation in accordance with ASC 718, Compensation—Stock Compensation, or ASC 718. ASC 718 requires the recognition of compensation expense, using a fair-value-based method, for costs related to all share-based payments including stock options. ASC 718 requires companies to estimate the fair value of share-based payment awards on the date of grant. Our determination of the fair value of stock options with time-based vesting on the date of grant utilizes the Black-Scholes option-pricing model. We estimate the expected

option lives using historical data, volatility using stock prices of peer companies, risk-free rates using the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term equal to the expected term, and dividend yield using our expectations and historical data. We use the simplified method to calculate the expected term of employee stock option grants. Under the simplified method, the expected term is estimated to be the mid-point between the vesting date and the contractual term of the option. For awards with graded vesting, in which specified tranches of the options vest on different dates, we use a single weighted-average expected life to value the entire award, which is equal to the average of the weighted-average vesting period of the award and the contractual term of the award. The fair value of each stock option grant is calculated based upon our common stock valuation on the date of the grant. Equity instruments issued to nonemployees are recorded at their fair value on the grant date and without subsequent remeasurement. The amount of stock-based compensation expense recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest, including awards with graded vesting. As part of the requirements of ASC 718, we have elected to account for forfeitures of stock option grants as they occur.

Fair value of common stock

Historically, for all periods prior to this offering, the fair value of our common stock was estimated on each grant date by our board of directors. In order to determine the fair value, our board of directors considered, among other things, contemporaneous valuations of our common stock and preferred stock prepared by unrelated third-party valuation firms in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid.

Given the absence of a public trading market of our shares of capital stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our shares of common stock and preferred stock, including:

- the prices at which we sold shares of convertible preferred stock and the superior rights and preferences of the convertible preferred stock relative to its common stock;
- the progress of our research and development programs, including the status and results of nonclinical studies for its product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- our financial position, including cash on hand, and its historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and convertible preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biotechnology industry.

Significant changes to the key assumptions underlying the factors used could have resulted in different fair values of common stock at each valuation date.

Common stock valuation methodology

Our contemporaneous common stock valuations were prepared in accordance with the guidelines in the Practice Aid, which prescribes several valuation approaches for determining the value of an enterprise, such as the cost, market and income approaches, and various methodologies for allocating the value of an enterprise to its capital structure and specifically the common stock.

In determining the fair value of our common stock through December 31, 2018, we estimated the equity value of our business using income and market approaches including recent sales of our convertible preferred stock in

arms'-length transactions (the back-solve method). Once an equity value was determined, we utilized the Option-pricing method, or OPM, to allocate the overall value of equity to the various share classes. In accordance with the Practice Aid, the OPM was the most appropriate method for determining the fair value of our common stock based on our stage of development and other relevant factors. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value if the funds available for distribution to stockholders exceed the value of the liquidation preferences at the time of a liquidity event, such as a strategic sale or merger. The common stock is modeled as a call option on the underlying equity value at a predetermined exercise price. In the model, the exercise price is based on a comparison with the total equity value rather than, as in the case of a regular option, a comparison with a per share stock price. Thus, common stock is considered to be a call option with a claim on the enterprise at an exercise price equal to the remaining value immediately after the preferred stock liquidation preference is paid. The OPM uses the Black-Scholes option pricing model to price the call options. This model defines the fair value of securities as functions of the current fair value of a company and uses assumptions such as the anticipated timing of a potential liquidity event and the estimated volatility of the equity securities.

In determining the fair value of our common stock beginning May 2020, we estimated the equity value of our business using the Hybrid Method, which utilizes the Probability-Weighted Expected Return Method, or PWERM, a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for us assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. A discount for lack of marketability is then applied to the common stock to account for the lack of access to an active public market. The Hybrid Method is a PWERM where the equity value in one of the scenarios is calculated using an OPM. In the Hybrid Method used by us, we considered three types of future-event scenarios: an initial public offering, an unspecified liquidity event and a scenario where we remain a private company. The equity value for the initial public offering scenario was determined using the guideline public company method, or GPC, which includes comparisons to publicly-traded companies in our industry that recently completed initial public offerings. The equity value for the unspecified liquidity event scenario was determined using a back-solve method. The relative probability of each type of future-event scenario was determined based on an analysis of market conditions at the time, including then-current initial public offering valuations of similarly situated companies, and our expectations as to the timing and likely prospects of the future-event scenarios. A discount for lack of marketability is then applied to the common stock to account for the lack of access to an active public market. To derive the fair value of the common stock for each scenario using the Hybrid Method, we calculated the proceeds to the common stockholders based on the preferences and priorities of the convertible preferred stock and common stock. We then applied a discount for lack of marketability to the common stock to account for the lack of access to an active public market.

We performed contemporaneous valuations, with the assistance of a third-party valuation specialist, as of December 31, 2018, May 31, 2020, July 31, 2020 and August 31, 2020, which resulted in valuations of our common stock of $0.725, $2.064, $4.406 and $4.824 per share, respectively. We had initially used an OPM in assessing the fair value of our common stock as of May 31, 2020. For financial reporting purposes in connection with the current initial public offering process, we retrospectively assessed the fair value of our common stock in connection with our June 2020 stock option grants and restricted stock awards using the Hybrid Method. See the column titled "Estimated Fair Value of Common Stock Per Share on Grant Date (utilized for ASC 718 calculation)" in the table below.

Following the closing of this offering, the fair value of our common stock will be determined based on the closing price of the primary stock exchange on which our common stock is traded.

Stock options and restricted stock awards

The following table sets forth by grant date the number of shares subject to stock options granted from January 1, 2019 through September 30, 2020, the per share exercise price of the options, the fair value of common stock per share on each grant date, and the per share estimated fair value of the options:

Grant Date	Number of Shares Subject to options Granted	Per Share Exercise Price of options	Estimated Fair Value of Common Stock Per Share on Grant Date (utilized for ASC 718 calculation)	Per Share Estimated Fair Value of Options
June 10, 2020	78,128	$ 2.064	$ 2.398	$ 1.59
June 10, 2020	344,537	$ 2.064	$ 2.398	$ 1.62
August 12, 2020	306,612	$ 4.406	$ 4.405	$ 2.87
August 12, 2020	105,451	$ 4.406	$ 4.405	$ 2.93
August 14, 2020	15,781	$ 4.406	$ 4.405	$ 2.96
September 12, 2020	227,859	$ 4.824	$ 4.823	$ 3.18
September 18, 2020	113,928	$ 4.824	$ 4.823	$ 2.98
September 19, 2020	82,931	$ 4.824	$ 4.823	$ 3.18
September 19, 2020	1,280,026	$ 4.824	$ 4.823	$ 3.21

In June 2020, we granted to certain employees 789,096 shares of restricted stock. The restricted stock was issued as consideration for services at a deemed fair value per share of $2.40, for aggregate consideration of $1.9 million.

Accrued research and development expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing purchase orders and open contracts, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by CROs and CMOs among others, in connection with research and development activities for which we have not yet been invoiced.

We contract with CROs and CMOs to conduct clinical and manufacturing and other research and development services on our behalf. We base our expenses related to CROs and CMOs on our estimates of the services received and efforts expended pursuant to quotes and contracts with them. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our CROs or CMOs will exceed the level of services provided and result in a prepayment of the research and development expense. 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 the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Emerging growth company status

The JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition to comply with new or revised accounting standards applicable to public companies until those standards would

otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we are (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition provided in the JOBS act. As a result, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies and our financial statements may not be comparable to other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. The JOBS Act also exempts us from having to provide an auditor attestation of internal control over financial reporting under Sarbanes-Oxley Act Section 404(b).

We will cease to be an "emerging growth company" on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (ii) the last day of the fiscal year in which the fifth anniversary of the completion of this initial public offering occurs, (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (iv) the last day of the fiscal year in which we are deemed to be a large accelerated filer under the rules of the SEC, which generally is when we have more than $700.0 million in market value of our stock held by non-affiliates as of the last day of the second fiscal quarter and we have been a public company for at least 12 months and have filed one annual report.

Further, even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exceptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our shares of common stock less attractive because we may rely on these exemptions. If some investors find our shares of common stock less attractive as a result, there may be a less active trading market for shares of our common stock and our share price may be more volatile.

Recently issued accounting pronouncements

See Note 2 to our financial statements beginning on page F-1 of this prospectus for a description of recent accounting pronouncements applicable to our financial statements.

Qualitative and quantitative disclosures about market risk

Interest rate risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. As of December 31, 2019 and September 30, 2020, we had cash and cash equivalents of less than $0.1 million and $127.8 million, respectively. We generally hold our cash in interest-bearing bank accounts and money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. An immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash.

Financial institution risk

Substantially all of our cash is held with a single financial institution. Due to its size, this financial institution represents a minimal credit risk. Cash amounts held at financial institutions are insured by the Federal Deposit Insurance Corporation up to $250,000.

Foreign currency exchange risk

Our expenses are generally denominated in U.S. dollars. To date, we have not had any foreign currency transactions, and we do not have a formal hedging program with respect to foreign currency. A 10.0% increase or decrease in current exchange rates would not have a material effect on our financial results.

Effects of inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented.

Business

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of next generation targeted therapies for women's cancers. Our team has spent the past decade characterizing the structure and function of the estrogen receptor, or ER, a key driver of breast cancer in approximately 75% of patients, in order to develop more potent, oral therapies that completely inactivate this signaling pathway. Our lead product candidate, OP-1250, is a novel oral therapy with combined activity as both a complete ER antagonist, or CERAN, and a selective ER degrader, or SERD, which we believe will drive deeper, more durable responses than existing therapies. OP-1250, both as a monotherapy and in combination with inhibitors of cyclin-dependent kinase 4 and 6, or CDK4/6, demonstrated robust tumor shrinkage in several xenograft models, including a breast cancer brain metastasis model. In August 2020, we initiated an ongoing Phase 1/2 dose escalation and expansion trial evaluating OP-1250 for the treatment of recurrent, locally advanced or metastatic ER-positive, or ER+, human epidermal growth factor receptor 2-negative, or HER2-, breast cancer, and expect to report initial data from this trial in the second half of 2021. We own worldwide development and commercialization rights to OP-1250. We believe OP-1250's oral formulation and dual mechanism of action directly address the limitations of current endocrine therapies, such as fulvestrant and tamoxifen, and position OP-1250 as a potential endocrine therapy of choice for the treatment of ER+ breast cancers. Our goal is to transform the standard of care for women living with cancers by developing more effective therapies that apply our deep understanding and collective expertise in endocrine-driven cancers, nuclear receptor activities and mechanisms of acquired resistance.

We are initially focused on developing therapies for the treatment of breast cancer, which represents approximately 30% of all new diagnoses of women's cancer. In 2020, the American Cancer Society, or ACS, estimates there will be approximately 276,000 new cases of female breast cancer and over 42,000 deaths from metastatic breast cancer in the United States. Treatment decisions are based on a combination of individual patient characteristics and tumor biology, most importantly the expression of three proteins: ER, progesterone receptor, or PR, and human epidermal growth factor receptor 2, or HER2. Approximately 75% of all breast cancers are ER+, and approximately 65% are ER+/HER2- highlighting the central role of the ER in driving a large majority of breast cancer. Approximately 6-10% of breast cancer patients present with metastatic disease at diagnosis and a further 20-30% of patients initially diagnosed with early-stage disease ultimately develop metastatic disease. The current five-year survival rate for patients with ER+ metastatic breast cancer is approximately 30%. In 2019, worldwide sales for endocrine and targeted therapies treating ER+ breast cancer patients totaled $9.6 billion.

The ER is a nuclear receptor that functions as a ligand regulated transcription factor. When bound to estrogen, the ER directs the expression of genes that are essential for breast cancer cells' survival and proliferation. For more than four decades, researchers have been developing new approaches and therapies to prevent activation of the ER pathway, thereby inhibiting the ability of the ER to drive tumor cell growth. In 1977, the first endocrine therapeutic, the anti-estrogen tamoxifen, was approved by the U.S. Food and Drug Administration, or FDA, for the treatment of breast cancer. Tamoxifen is still commonly used today but is challenged by the development of acquired drug resistance, which in some cases may be due to its partial agonist activity. In search for a different mechanism to target the estrogen pathway, aromatase inhibitors, or AIs, were developed in the 1990s to block the synthesis of estrogen and deprive the ER+ cells of its activating ligand. However, up to 50% of patients taking AIs develop arthralgia, leading to suspension of treatment in up to 15% of patients. Additionally, most patients with metastatic breast cancer have been shown to ultimately develop resistance to AIs. These agents are also not used to treat pre-menopausal women without the addition of ovarian suppression.

In 2002, fulvestrant was approved as a treatment for hormone receptor positive, or HR+, metastatic breast cancer patients and is typically used as a second- or third-line endocrine agent. Fulvestrant was designed to be a CERAN, and later discovered to also be a SERD, and represented a breakthrough for the field with improved outcomes for patients whose disease had progressed on prior endocrine therapy. However, fulvestrant has several limitations including its suboptimal drug exposure and route of administration as a monthly intramuscular injection. Despite these drawbacks, fulvestrant achieved worldwide sales of over $1.1 billion in 2019.

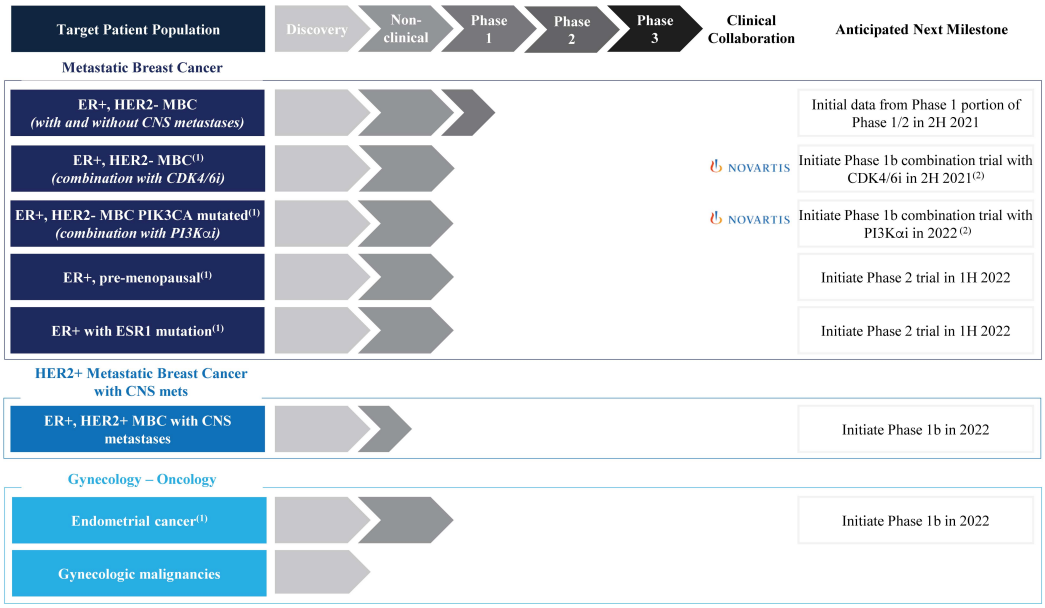
More recently, the field has focused on the discovery and development of oral agents that have fulvestrant's dual mechanism of action to completely inactivate and degrade the ER. Some of these oral SERD agents are CERANs, such as OP-1250, but others have partial agonist activity despite being SERDs and thus are not CERANs. SERDs reduce the levels of the ER but they do not entirely eliminate it. Consequently, SERDs are not necessarily CERANs. Notably, estrogen itself leads to ER degradation.

We designed our lead product candidate, OP-1250, based both on a detailed structural understanding of the ER and on known alterations to this structure induced by fulvestrant and other ligands. We have demonstrated in nonclinical studies that OP-1250 functions both as a CERAN and a SERD, but is distinguished from fulvestrant in several noteworthy ways, including:

- *OP-1250 is orally bioavailable while fulvestrant is a highly insoluble compound that must be administered monthly by intramuscular injection into the buttocks;*
- *OP-1250 has favorable biodistribution properties leading to higher drug concentrations in the plasma and tumor than those achieved with fulvestrant, as shown in a head-to-head mouse xenograft study; and*
- *OP-1250 has demonstrated the ability to shrink tumors in head-to-head nonclinical studies with fulvestrant, in contrast to fulvestrant, which has only been shown to inhibit tumor growth.*

Based on these nonclinical differences, we believe that OP-1250 has the potential to demonstrate clinical outcomes superior to fulvestrant. Furthermore, OP-1250 has the potential to benefit patients with metastatic breast cancer, initially for patients who have previously received endocrine therapy, as well as those who are treatment naïve in the metastatic setting, and advance into the adjuvant setting for early-stage ER+ breast cancer. In multiple nonclinical animal models of anti-cancer activity, including patient-derived xenografts with tumors containing activating mutations in the ER, OP-1250 monotherapy led to tumor shrinkage or in some cases tumor eradication, as well as long-term post-treatment survival. In each of these nonclinical models, the effect of OP-1250 was superior to that of fulvestrant, an effect which we determined was driven both by improved pharmacokinetic, or PK, properties, and higher plasma and tumor drug concentrations. In nonclinical studies, OP-1250 demonstrated robust central nervous system, or CNS, penetration, and in an intracranial breast cancer brain metastases xenograft study, OP-1250 demonstrated the ability to shrink tumors and improve survival in mice. OP-1250 has the potential to address a critical unmet need as 10-15% of ER+ breast cancer patients develop brain metastases for which there are currently limited treatment options.

As summarized in the figure below, our plan is to develop our wholly-owned lead product candidate, OP-1250, in a number of ER+ breast cancer indications, both as a monotherapy and in combination with approved targeted therapies that have shown improved outcomes with other endocrine therapies.



MBC = metastatic breast cancer; PI3Kα = phosphatidylinositol 3-kinase alpha; RP2D = recommended Phase 2 dose; CDK4/6i = CDK4/6 inhibitor; PI3Kαi = PI3Kα inhibitor

(1) Patient population may be studied as additional cohort(s) of current Phase 1/2 clinical trial or may be studied in a separate clinical trial.

(2) Anticipated initiation of Phase 1b is after determination of RP2D of current Phase 1/2 trial.

In August 2020, we initiated a Phase 1/2 clinical trial of OP-1250 in patients with recurrent, locally advanced or metastatic ER+/HER2- breast cancer whose disease has progressed on endocrine therapy. Phase 1 consists of monotherapy dose escalation to evaluate the safety and PK of OP-1250 and to determine the maximum tolerated dose, or MTD, and/or the recommended Phase 2 dose, or RP2D. The expansion phase will enroll patients at the RP2D in order to explore preliminary efficacy in selected patient populations. The first cohort of the expansion phase will consist of women and men with recurrent, locally advanced or metastatic breast cancer whose disease has progressed on prior endocrine therapy. A second cohort is exploratory and will enroll individuals with metastatic breast cancer who have brain metastases. As of October 23, 2020, the first dose cohort, consisting of four patients, has completed enrollment and the initial 28 day dose limiting toxicity assessment period, and the second dose cohort is enrolling patients. Preliminary PK data from the first dose cohort is consistent with nonclinical modeling of our Phase 1 starting dose. We expect to report initial data from the Phase 1 portion of the trial in the second half of 2021. In addition, we plan to explore the potential clinical benefit of OP-1250 in combination with other approved agents for breast cancer, such as inhibitors of CDK4/6 and phosphatidylinositol 3-kinase alpha, or PI3Kα, which have been shown to lead to improvements in both progression-free and overall survival. In July 2020, we entered into a non-exclusive agreement with Novartis Institutes for BioMedical Research, Inc., or Novartis, to evaluate the combination of OP-1250 and Novartis' ribociclib, a CDK4/6 inhibitor, as well as alpelisib, their PI3Kα inhibitor. Under the terms of the collaboration, Novartis will be responsible for funding a capped majority of the costs for the Phase 1b clinical trial, as well as supplying their drugs.

Our Chief Technology Officer, Cyrus Harmon, Ph.D., and Chief Scientific Officer, Peter Kushner, Ph.D., co-founded the company in 2007 with the goal of discovering and developing therapies to improve the lives of women with cancer. Our management team has significant experience in oncology and in progressing products from early stage research to clinical trials, and ultimately to regulatory approval and commercialization. Together, they bring in-house expertise in medicinal chemistry, biology, translational medicine, computational biology and chemistry, in vitro and in vivo pharmacology, biomarker development and manufacturing. We have also established internal expertise in clinical development, clinical operations, pharmacovigilance, clinical pharmacology, regulatory and quality. Our Chief Executive Officer, Sean Bohen, M.D., Ph.D., was previously the Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca. Prior to AstraZeneca, Dr. Bohen

held various leadership roles during his 13 years at Genentech including Senior Vice President, Early Development. Other members of the management team have held senior level positions at Neomorphic (sold to Affymetrix), Serra Pharmaceuticals (sold to Karo Bio), Genentech, BlueRock Therapeutics (sold to Bayer AG), Intellikine (sold to Takeda), Kosan Biosciences (sold to Bristol-Myers Squibb), PTC Therapeutics, Portola Pharmaceuticals (sold to Alexion), Alexion Pharmaceuticals and Elan Corporation (sold to Perrigo). We are supported by our board of directors, scientific advisory board and a leading syndicate of investors which includes Avoro Capital Advisors, funds and accounts managed by BlackRock, BVF Partners L.P., Cormorant Asset Management, Deerfield Management Company, Foresite Capital, Janus Henderson Investors, Logos Capital, OrbiMed, RA Capital Management, Surveyor Capital (a Citadel company), Venrock Healthcare Capital Partners, Vivo Capital and Wellington Management.

Our strategy

Our goal is to discover, develop and commercialize next generation targeted therapies for women's cancers. The key elements of our business strategy to achieve this goal include:

- **Applying our deep understanding of nuclear receptors — particularly the ER — and mechanisms of resistance to develop novel therapeutic approaches for endocrine-driven cancers.** Our team has spent over a decade characterizing the structure and function of the ER and its role in driving tumor cell proliferation in HR+ breast cancer. Our knowledge of the ER's functional domains combined with our medicinal chemistry expertise has allowed us to develop a potent and oral compound that both completely inactivates and strongly promotes degradation of the ER in nonclinical studies. We believe OP-1250's oral formulation and dual mechanism of action as a CERAN/SERD directly address the limitations of current endocrine therapies, such as fulvestrant and tamoxifen, and has the potential to drive deeper, more durable responses.
- **Rapidly advancing our lead product candidate, OP-1250, through clinical development as a monotherapy for ER+/HER2- breast cancer.** We are currently evaluating OP-1250 monotherapy in a Phase 1/2 dose escalation and expansion clinical trial in patients with recurrent, locally advanced or metastatic ER+/HER2- breast cancer whose disease has progressed on endocrine therapy. We expect to report initial data from this trial in the second half of 2021. After examining safety and PK as well as determining the RP2D, we intend to advance OP- 1250 into Phase 2 dose expansion cohorts, and to study OP-1250 in patients with earlier stage disease. We also plan to study OP-1250 in selected breast cancer populations, including pre-menopausal women and patients with mutations in the estrogen-binding domain of ESR1, the gene that encodes the ER.
- **Establishing OP-1250 as the endocrine therapy of choice with targeted therapy combinations for the treatment of metastatic ER+ breast cancers.** We believe OP-1250's differentiated product profile has the potential to overcome many of the limitations of current treatment options. We plan to explore the potential clinical benefit of OP-1250 in combination with other approved agents for breast cancer, such as inhibitors of CDK4/6 and PI3Kα, which have been shown to lead to improvements in both progression-free and overall survival. At low concentrations in nonclinical models, OP-1250 worked in combination with inhibitors of CDK4/6 and PI3Kα. In July 2020, we entered into a non-exclusive agreement with Novartis to evaluate the combination of OP-1250 and ribociclib, a CDK4/6 inhibitor as well as alpelisib, a PI3Kα inhibitor. Our goal is to successfully demonstrate improved efficacy and a favorable tolerability profile in combination with other targeted therapies in order to position OP-1250 as the endocrine therapy of choice.
- **Exploring additional clinical opportunities for OP-1250, including metastatic breast cancer with brain metastases and other hormone sensitive tumors.** Metastatic breast cancer is the second most common cancer associated with brain metastases in the United States. Of women with ER+ metastatic breast cancer, 10-15% will develop brain metastases, which present a significant challenge to systemic therapy. The primary treatment for CNS metastases is typically surgery, radiation, or a combination of both and these patients tend to have a poor prognosis. In nonclinical studies, OP-1250 demonstrated robust CNS penetration, and in an intracranial breast cancer brain metastases xenograft study, OP-1250 demonstrated the ability to shrink tumors and improve survival in mice. In addition, combining OP-1250 with HER2 targeted agents may represent an opportunity to improve upon recent advancements in the treatment of CNS disease in patients that express both ER and HER2,

as up to 50% of patients with metastatic HER2+ breast cancer develop CNS disease, and the majority of patients with HER2+ breast cancer also express ER. In addition to breast cancer, we intend to explore the use of OP-1250 in various gynecological malignancies, beginning with endometrial cancer. Approximately 80% of endometrial tumors are “endometriod” in nature and these tumors are driven by estrogen.

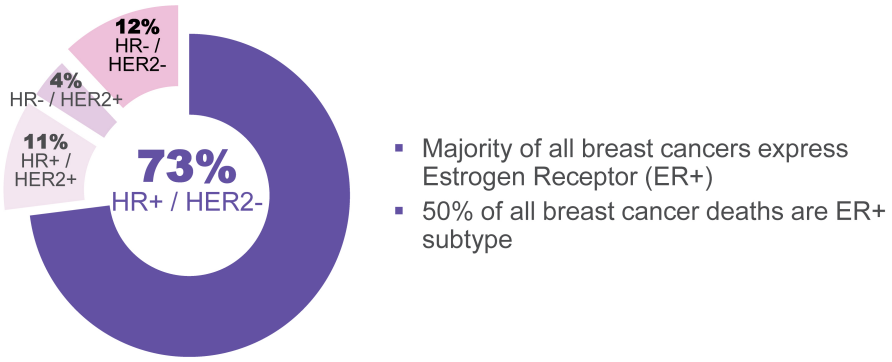
- **Continuing to evaluate opportunities to accelerate development timelines and enhance the commercial potential of our programs in collaboration with third parties.** We own full worldwide development and commercialization rights to OP-1250. We have established a clinical collaboration with Novartis and intend to continue evaluating opportunities to work with partners that meaningfully enhance our capabilities with respect to the development and commercialization of OP-1250. In addition, we intend to commercialize our product candidates in key markets either alone or with partners in order to maximize the worldwide commercial potential of our programs.
- **Expanding our portfolio of therapies focused on women’s oncology through both internal research activities and business development efforts.** We are applying our internal drug discovery capabilities to identify and evaluate novel targeted therapies that can improve the lives of women with cancer. We will continue to explore opportunities to acquire products and technologies that align with our core areas of expertise and complement our existing portfolio.

Our opportunity

Epidemiology and classification of breast cancer

Breast cancer is the second-most common cancer worldwide, with nearly 2 million new diagnoses per year. In 2020, the ACS estimates there will be approximately 276,000 new cases of female breast cancer and over 42,000 deaths in the United States, making it the second-leading cause of cancer death in women. Approximately 2,500 men are also diagnosed with breast cancer each year in the United States. Breast cancer is a heterogeneous disease which is grouped into several clinical subtypes based on the expression of three proteins: ER, PR and HER2. Both ER and PR are hormone receptors, and tumors that express either of these receptors are referred to as HR+. It is unusual for a tumor to express PR in the absence of the ER, therefore most tumors are referred to as either ER+ or ER-. Tumors that express HER2 are denoted HER2+, and tumors that do not express ER, PR or HER2 are classified as triple negative breast cancer. Approximately 75% of all breast cancers are ER+, and approxmiately 65% are ER+/HER2-, highlighting the central role of ER signaling in driving a large majority of breast cancer. The percentage breakdown of all breast cancers by subtype are shown in the Figure 1.

Figure 1. Types of breast cancer



Treating breast cancer

Early-stage breast cancer

Breast cancer stage is determined by the size of the tumor and whether or not the cancer has spread to lymph nodes. A tumor that is confined to the breast with or without the involvement of local, ipsilateral lymph nodes is

considered early-stage breast cancer. Treatment for patients with early-stage breast cancer involves two components. First, there is local treatment of the breast, chest wall and local lymph nodes, if any, with surgery, either a lumpectomy or mastectomy, and potentially radiation. Second, based on the biology and characteristics of the tumor, patients may also be offered systemic therapy, referred to as adjuvant therapy, in order to decrease the risk of recurrence of breast cancer anywhere in the body. Systemic therapy can be given either after surgery (adjuvant) or prior to surgery (neoadjuvant) or a combination of both.

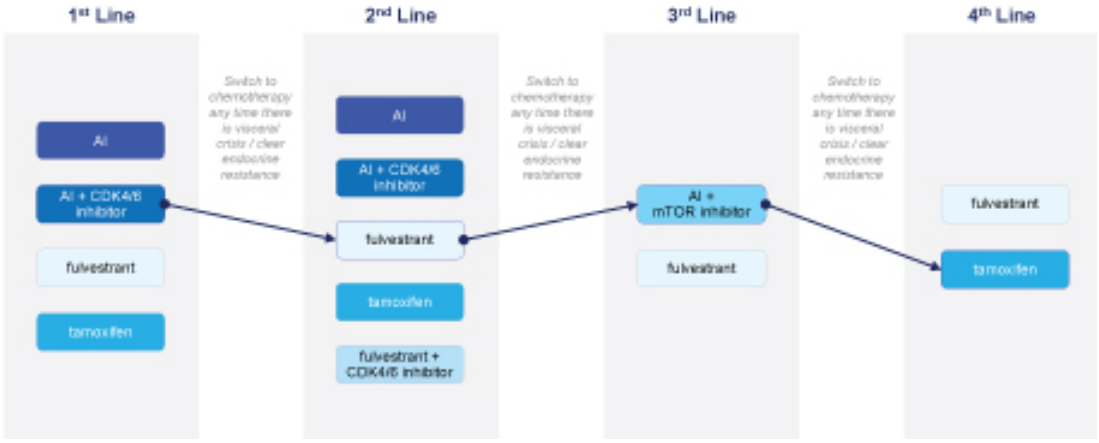
The initial standard of care for patients with early-stage ER+ breast cancer is at least five years of adjuvant endocrine therapy. The endocrine treatment options for early-stage disease are AIs, such as anastrozole, exemestane or letrozole, or an ER antagonist such as a tamoxifen. For patients diagnosed with early-stage ER+ breast cancer who undergo surgical and adjuvant/neoadjuvant treatment, the five-year survival rate is over 90%.

Metastatic breast cancer

When cancer has spread beyond local lymph nodes, either to distant lymph nodes, bones or visceral organs, the cancer is now considered metastatic. Approximately 6-10% of breast cancer patients present with *de novo* metastatic disease, also referred to as stage IV disease, at initial diagnosis. In addition, approximately 20-30% of patients diagnosed with early-stage breast cancer will develop metastatic disease. In contrast to the goals of adjuvant therapy, treatments for metastatic disease are palliative with the desired outcome of controlling symptoms and extending survival as long as possible. The current five-year survival rate for patients with ER+ metastatic breast cancer is approximately 30%.

While there are national guidelines and recommendations for the treatment of metastatic breast cancer, the actual treatment decision is based on a combination of individual patient characteristics and tumor biology, including whether they received adjuvant therapy and if so, how quickly the cancer recurred. There is significant overlap in the agents that are recommended, but guidelines vary in the sequence in which these agents are used. In the past five years, several new classes of targeted therapies have been approved to be used in combination with endocrine agents for the treatment of HR+/HER2- breast cancer. Inhibitors of CDK4/6, such as palbociclib, ribociclib and abemaciclib, used in combination with an AI or fulvestrant, led to significant increases in progression-free survival and overall survival. Alpelisib, a PI3Kα inhibitor, was approved in 2019 in combination with fulvestrant for the treatment of HR+/HER2- breast cancers that have mutations in PIK3CA. Figure 2 shows the endocrine treatment options available for ER+ metastatic breast cancer, and an example of the sequence of treatments, by agent and line of therapy.

Figure 2. Available endocrine options and example of sequential alternating of endocrine based therapy in ER+ metastatic breast cancer



When moving a patient from one line of therapy to the next, the standard of care is to switch to an endocrine agent with a different mechanism of action depending upon last therapy, co-morbidities, and individual patient characteristics.

Metastatic breast cancer is the second most common cancer associated with brain metastases in the United States. About 10-15% of women with metastatic breast cancer develop brain metastases. Brain metastases present a significant challenge to systemic therapy, and the primary treatment for CNS metastases is typically surgical resection, radiation, or a combination of both. Given the limited treatment options available for these patients, the prognosis remains poor, making it an area of continued, high unmet medical need. In addition, brain metastases in breast cancer patients are a major cause of morbidity, associated with progressive neurologic deficits that result in a reduced quality of life.

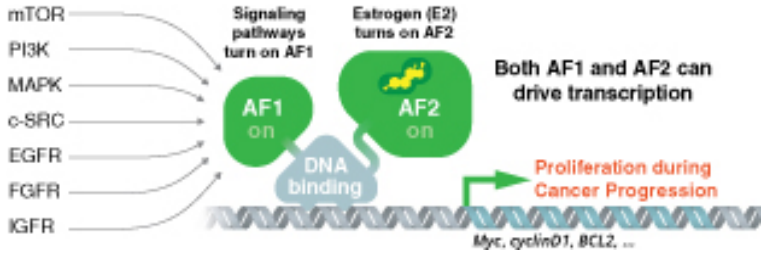
ER signaling in cancer

The ER is a nuclear receptor that functions as a ligand regulated transcription factor. When bound to estrogen, the ER directs the expression of genes that are essential for breast cancer cells' survival and proliferation. The ER has three modular functional domains:

- The amino terminal domain, which contains the activation function 1, or AF1, the activity of which can be increased by multiple cell proliferative signaling pathways;
- The DNA binding domain, which directs the ER to bind to a specific set of ER-responsive genes; and
- The ligand binding domain, which contains the activation function 2, or AF2, which is turned on when bound to estrogen.

Activation of either AF1 or AF2 can drive transcription and cancer cell proliferation.

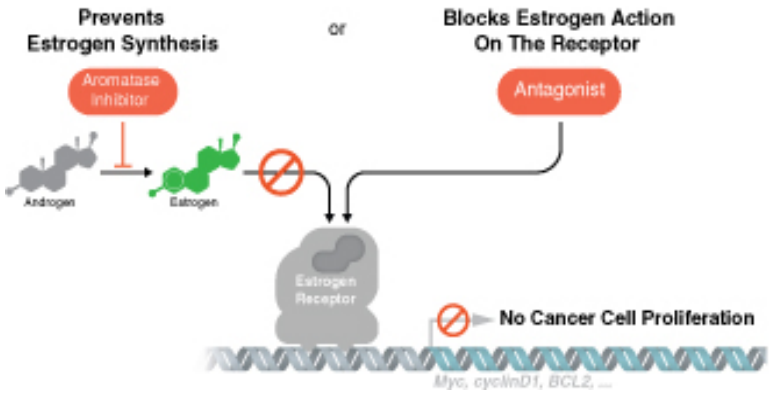
Figure 3. ER is a tripartite protein with two distinct transcription factor activation domains, AF1 and AF2



Classes of endocrine therapies and their limitations

For more than four decades, researchers have been developing new approaches and therapies to prevent activation of the ER pathway, thereby inhibiting the ability of the ER to drive tumor cell growth. Figure 4 describes the two major classes of endocrine therapies, AIs and ER antagonists. In 2019, worldwide sales for endocrine and targeted therapies treating ER+ breast cancer patients totaled $9.6 billion.

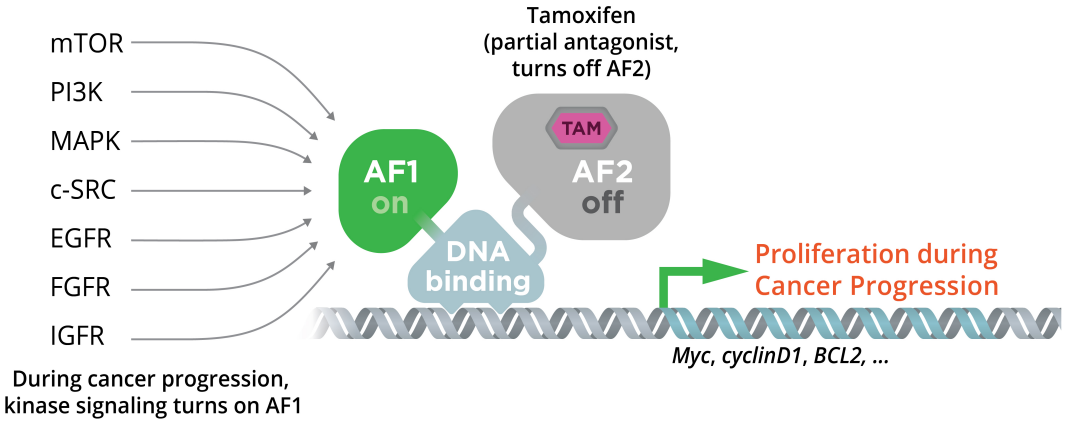
Figure 4. Classes of endocrine therapies



Antagonists with partial agonist activity

In 1977, the first endocrine therapeutic, tamoxifen, was approved by the FDA for the treatment of breast cancer. Although tamoxifen directly competes with estrogen and prevents activation of the AF2 transcription factor activation domain, it does not block AF1 activity and therefore does not completely inhibit ER function (Figure 5). As a consequence of this partial agonist activity, tamoxifen mimics estrogen in some circumstances and promotes proliferation. In addition, some breast cancers can develop resistance to these partial agonists by activation of upstream AF1 signaling pathways, such as mTOR, PI3K, MAPK, c-SRC, EGFR, FGFR and IGFR. Therefore, while tamoxifen is commonly used today, it is challenged by acquired drug resistance and a relatively short duration of response.

Figure 5. Partial agonists, such as tamoxifen, are unable to completely block ER activation



AIs

In search for a different mechanism to target the estrogen pathway, AIs were developed in the 1990s to block the synthesis of estrogen and deprive the ER+ tumor of its activating ligand. However, most patients with metastatic breast cancer have been shown to ultimately develop resistance to these therapies. Similar to tamoxifen, resistance to AIs, such as anastrozole, exemestane or letrozole, can develop by multiple mechanisms, including activation of the AF1 pathway and development of mutations. Mutations in ESR1 that confer estrogen-independent ER activity arise in 30-40% of patients receiving AI treatment.

SERDs

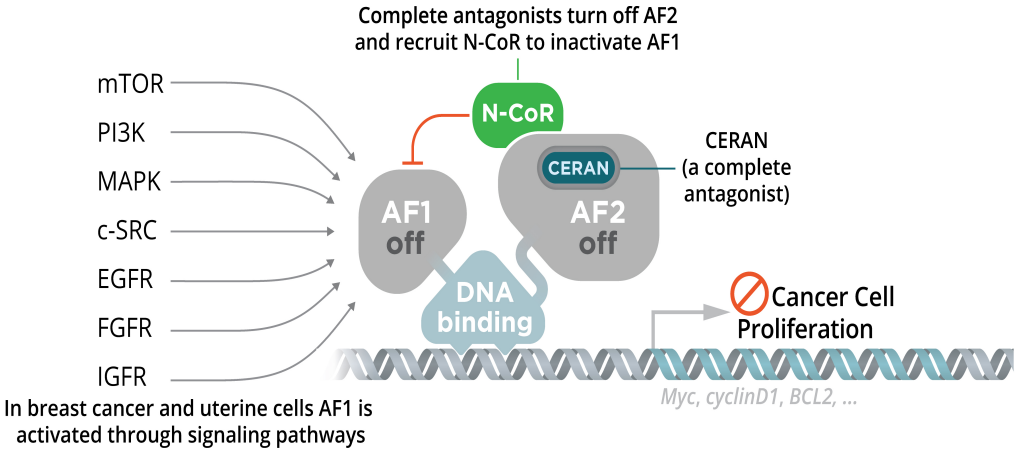
In the search for more potent ER antagonists, researchers focused on another class of ER drugs that were described as SERDs. This classification arose from the observation that certain ligands bind tightly to ER leading to ER degradation. The field shifted drug discovery efforts to SERDs based on the hypothesis that degrading ER would be more efficacious than inhibiting it. However, similar to tamoxifen, many compounds with SERD activity are not complete ER antagonists nor do they achieve complete degradation of the ER. Recent experiments conducted by us and third parties in nonclinical models of breast cancer suggest that ER degradation, as achieved by many SERDs, on its own is not sufficient to effectively treat tumors and that the ability to completely inhibit ER function is best achieved through complete antagonism.

CERANs

A CERAN is a molecule that completely blocks the ability of both AF1 and AF2 to stimulate gene transcription (Figure 6). CERANs inhibit activation of the AF2 transcription factor activation domain and inactivate AF1 activity by recruiting nuclear receptor corepressors of the N-CoR/SMRT family. Previous work by one of our co-founders identified specific interactions between fulvestrant-bound ER and N-CoR and that the strength of these interactions

correlated with the ability of fulvestrant-bound ER to inactivate gene transcription through the transcription factor activating domain, AF1.

Figure 6. CERANs block AF1 and AF2 activity inhibiting cell proliferation



CERANs block AF1 activity, even in the presence of signaling, inhibiting cell proliferation

In 2002, fulvestrant was approved as a treatment for HR+ metastatic breast cancer and is typically used as a second- or third-line endocrine agent. Fulvestrant represented a breakthrough for the field based on its dual-mechanism of action as a CERAN and SERD which led to improved efficacy outcomes for patients. However, fulvestrant, the only FDA-approved anti-estrogen lacking agonist-type effects in *in vivo* uterotropic assays in immature or ovariectomized mice and rats, has several limitations including:

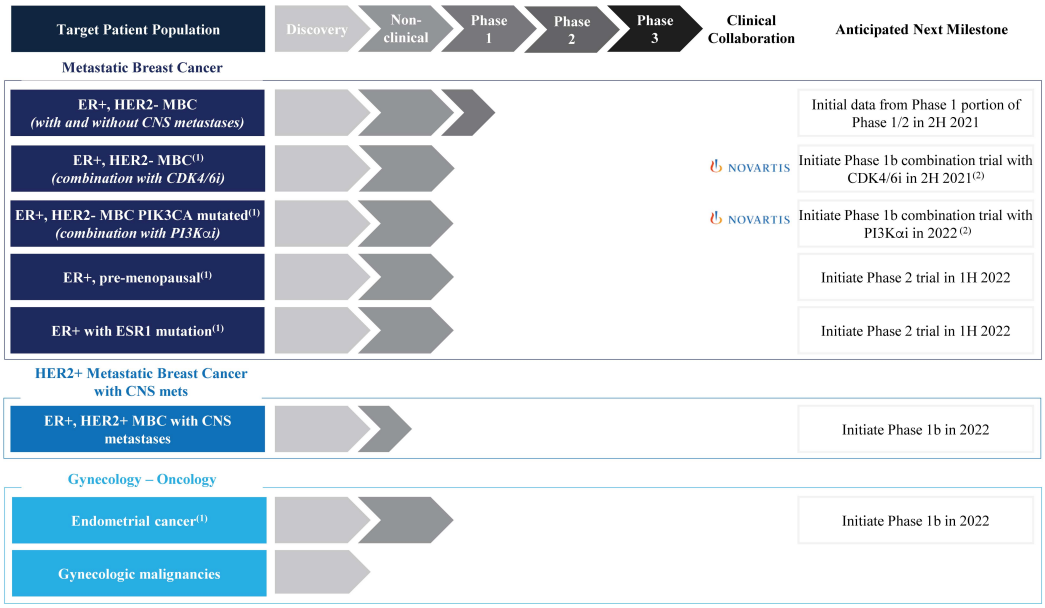
- *Painful and inconvenient route of administration.* Fulvestrant is a highly insoluble compound with poor oral bioavailability and therefore must be given intramuscularly. Fulvestrant is administered every 28-days in two 5 ml intramuscular injections into the buttocks. Injection site reactions occur in approximately 10% of patients and include sciatica, neuralgia, neuropathic pain, and peripheral neuropathy.
- *Suboptimal drug exposure limits efficacy.* In a nonclinical mouse model, an increase in antitumor activity and ER degradation was observed as the dose of fulvestrant was increased from 25 mg/kg to 200 mg/kg. However, researchers estimated that achieving an equivalent level of fulvestrant in humans to a 200 mg/kg dose in mice would require a dose that is eight times higher than is currently clinically achievable. Furthermore, xenograft models created using patient-derived tumors containing ESR1 mutations show that even plasma levels substantially higher than those achievable in humans at the approved dose fail to demonstrate optimal antitumor effect.

Despite the drawbacks of fulvestrant, it achieved worldwide sales of over $1.1 billion in 2019.

To address the limitations associated with available treatments for ER+ breast cancer patients, we believe an orally available, potent CERAN/SERD that both completely inactivates and strongly promotes degradation of the ER has the potential to become the endocrine therapy of choice for the treatment of ER+ breast cancers and drive deeper, more durable responses.

Our product candidate

We own worldwide development and commercialization rights to OP-1250. As summarized in the figure below, our plan is to develop OP-1250 for the treatment of a number of ER+ breast cancer indications, both as a monotherapy and in combination with approved targeted therapies that have shown improved outcomes with other endocrine therapies.



(1) *Patient population may be studied as additional cohort(s) of current Phase 1/2 clinical trial or may be studied in a separate clinical trial.*

(2) *Anticipated initiation of Phase 1b is after determination of RP2D of current Phase 1/2 trial.*

Our solution, OP-1250

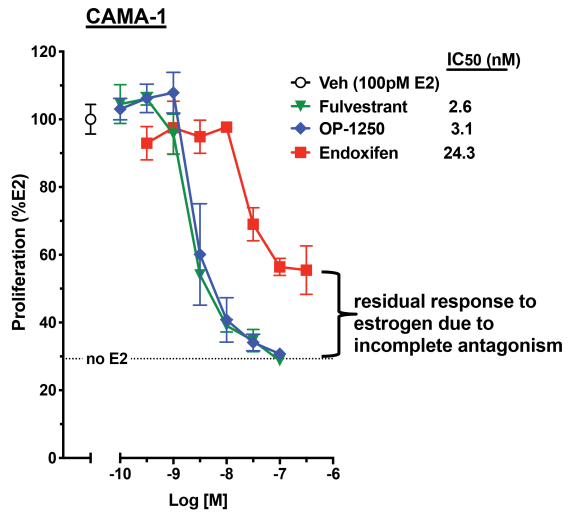
OP-1250 is an oral small molecule clinical-stage product candidate for the treatment of endocrine-driven cancers. OP-1250 was designed by our scientific team based both on a detailed structural understanding of the ER and on known alterations to this structure induced by fulvestrant and other ER ligands. We have demonstrated in nonclinical studies that OP-1250 functions both as a CERAN, inactivating both AF1 and AF2 transcriptional activation functions, and a SERD, promoting degradation of the ER. In several xenograft models, OP-1250, both as a monotherapy and in combination with CDK4/6 inhibitors demonstrated robust tumor shrinkage, including a breast cancer brain metastasis model. We are currently enrolling patients for our Phase 1/2 dose escalation and expansion trial for the treatment of recurrent, locally advanced or metastatic ER+/HER2- breast cancer, and expect to report initial data from this trial in the second half of 2021. We believe OP-1250's oral formulation and dual mechanism of action directly address the limitations of current endocrine therapies, such as fulvestrant and tamoxifen, and position OP-1250 as a potential endocrine therapy of choice for the treatment of ER+ breast cancers.

Nonclinical data

Potent anti-proliferative activity

In nonclinical studies, we found that OP-1250 was a potent inhibitor of proliferation and a strong degrader of the ER in multiple breast cancer cell lines. In a cell proliferation assay using CAMA-1 cells, a human breast cancer line that is partially resistant to tamoxifen, administration of OP-1250 led to concentration-dependent anti-proliferative activity with a half maximal inhibitory concentration, or IC_{50}, of 3.1 nM. The IC_{50} is the concentration of OP-1250 resulting in inhibiting estrogen-stimulated proliferation by 50%. We observed a similar potency in this cell line for fulvestrant. Endoxifen, a key active metabolite of tamoxifen, had a weaker potency in this assay, requiring a concentration of 24.3 nM to achieve an IC_{50}.

Figure 7. OP-1250 inhibits the proliferation of CAMA-1 cells



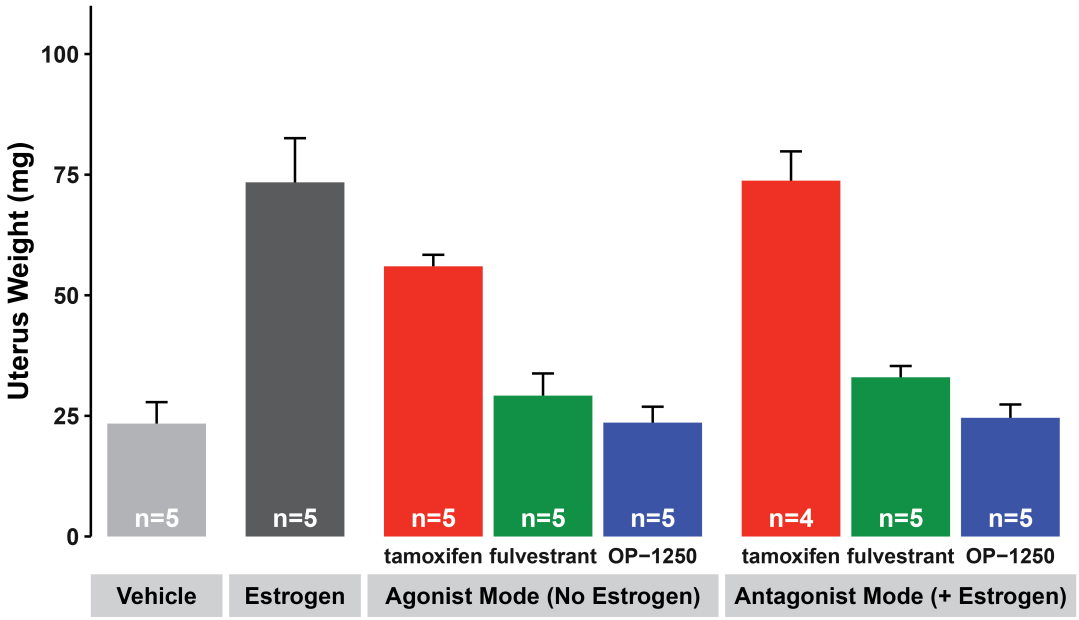
Ligand	Residual response to estrogen due to incomplete antagonism
Endoxifen	32%
ARN-810	13%
RAD1901	14%
AZD9496	7%
OP-1250	2%
Fulvestrant	-2%

In vitro cell proliferation experiment measuring DNA content after 8-day treatment of CAMA-1 breast cancer cells with ligands in the presence of 100 pM 17β-estradiol, or E2. Shown in the left side dose response graph of Figure 7 are mean values normalized to vehicle, or +E2, along with error bars representing the standard error of the mean, or SEM, from triplicate wells. Residual response to estrogen due to incomplete antagonism is the amount of proliferation remaining at saturating drug concentration relative to the proliferation seen in the absence of estrogen. Shown in the right side table of Figure 7 is mean percent residual proliferative response to estrogen calculated over multiple experiments after normalizing to +E2 (100%) and -E2 (0%) for endoxifen and some SERDs with incomplete antagonism, ARN-810, AZD9496, RAD1901, and the CERANS OP-1250 and fulvestrant.

Complete ER antagonism

A key distinguishing feature of CERANs is that they completely lack any agonistic estrogen-like effects, and completely block the effects of estrogen. A nonclinical model often used to assess the residual agonistic effect of ER antagonists is the ovariectomized mouse uterine weight model. In this model, removal of the ovaries eliminates the primary source of estrogen in the mouse and limits the development of uterine tissue. As shown in this head-to-head comparison study, dosing of these mice with estrogen leads to an increase in the weight of uterine tissue. Administration of tamoxifen in the absence of estrogen also results in an increase in uterine weight, illustrating that tamoxifen possesses some agonistic activity on ER in certain biological contexts. Furthermore, tamoxifen is unable to block the effect of estrogen in this model. Neither OP-1250 nor fulvestrant led to an increase in uterine weight in the absence of estrogen and both suppressed the stimulatory activity of estrogen, illustrating that OP-1250 and fulvestrant are CERANs.

Figure 8. OP-1250 and fulvestrant, both CERANs, lacked any ER agonistic activity and completely blocked ER activation by estrogen in an ovariectomized mouse uterine weight head-to-head comparison model

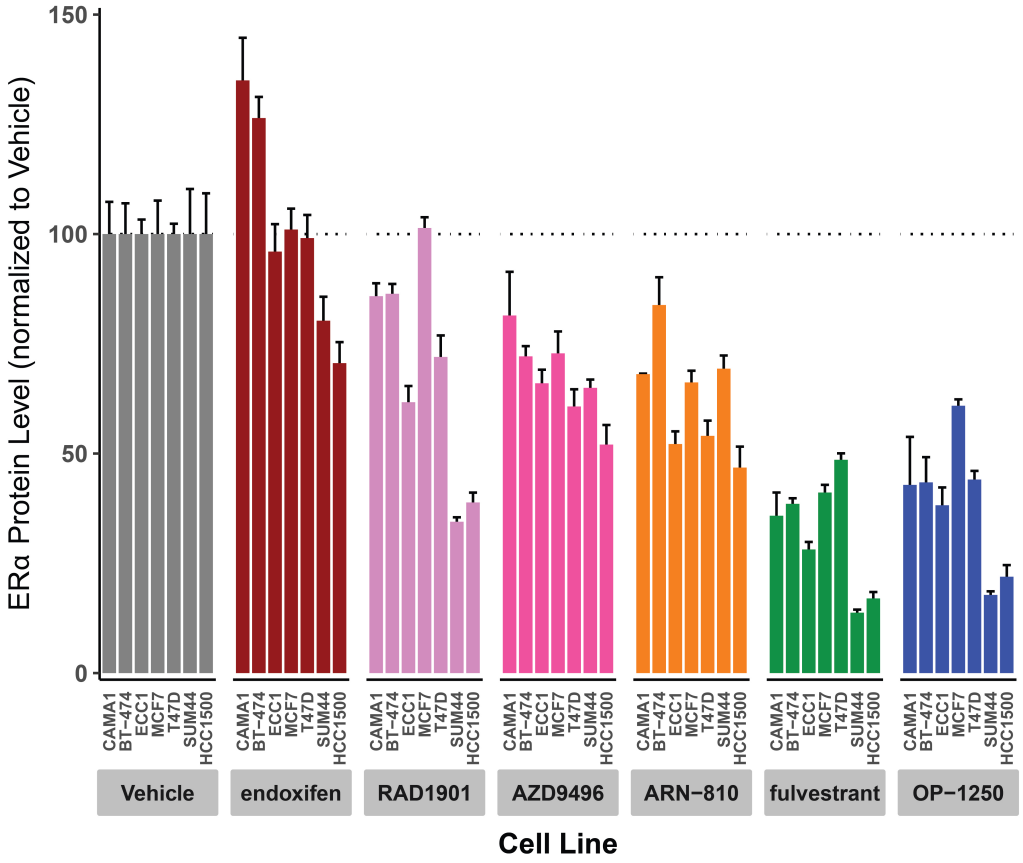


Uterine wet weight in ovariectomized BALB/c mice treated once daily for 3 days. Mice were treated with 100 mg/kg of OP-1250, 50 mg/kg of tamoxifen, 50µl of fulvestrant and/or 0.1 µg estrogen (E2). OP-1250 and tamoxifen were delivered orally, and E2 and fulvestrant were delivered subcutaneously.

SERD activity

SERDs are ER ligands that lead to partial degradation of the ER. This degradation takes place within four hours after exposure of cells to the SERD, indicating that it comes from destabilization of the ER protein. In a nonclinical analysis, we have tested the ability of OP-1250, fulvestrant and several non-CERAN SERDs (specifically, RAD1901, ARN-810, AZD9496) to degrade ER across seven different cell lines. As shown in Figure 9, after treatment of these cell lines for four hours, there was a dramatic difference in the effect on ER destabilization. Endoxifen, the active metabolite of tamoxifen, had virtually no effect and RAD1901, ARN-810 and AZD9496 degraded the ER to some degree in several of the cell lines. In contrast, fulvestrant and OP-1250 profoundly degraded the ER in each one of the cell lines, and the level of ER degradation for the cell lines treated with OP-1250 was consistent with that of fulvestrant.

Figure 9. OP-1250 degrades ER similarly to fulvestrant in seven tested cell lines.



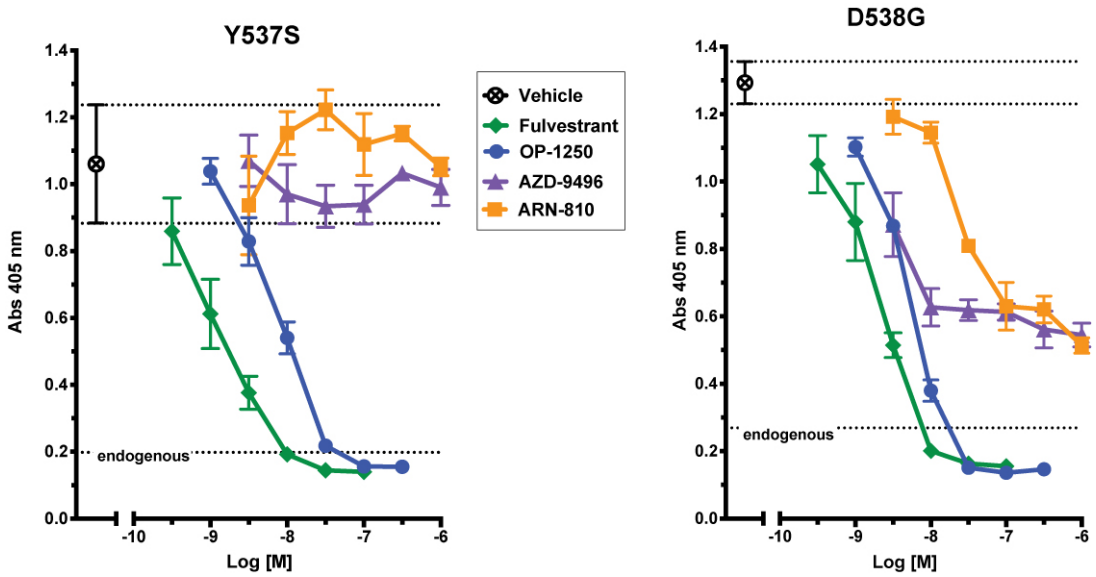
ERα protein levels were measured by western blot following treatment with indicated compound in a panel of six ER+ breast cancer cell lines (CAMA-1, BT-474, MCF-7, T47D, SUM44, HCC1500) and one ER+ endometrial cancer cell line. ERα protein levels by culturing breast cancer cell lines with 316 nM ligand in E2-depleted media for 4 hours. Protein lysates were immunoblotted with an antibody to ERα. Shown are mean ERα protein levels normalized to vehicle, and SEM from triplicate wells.

Potent antagonist activity on both wild-type and mutant ER

Treatment of breast cancers with AI therapy has been shown to lead to the development of resistance mutations in the ESR1 gene. These mutations are acquired during treatment and are found in less than 2% of untreated early-stage breast tumors but in 30-40% of metastatic tumors after treatment with AIs. More than 80% of mutations are found at three locations corresponding to amino acid residues 380, 537 and 538.

These mutations result in resistance to many estrogen therapies. We assessed the ability of estrogen compounds to inhibit ER-dependent transcription in cell lines containing ER alleles with mutations that have been found in patients. We used alkaline phosphatase, which is encoded by a gene activated by the ER primarily through the AF1 transcriptional activation function and has an enzymatic activity that can be readily measured in cells, as a surrogate for ER driven target gene transcription. We tested two clinical stage SERD compounds: ARN-810, also known as GDC-0810, a discontinued compound previously in Phase 2 clinical development by Genentech; and AZD9496, an AstraZeneca compound that has presented Phase 1 data. Both compounds were unable to fully inhibit the activity of the mutant ER. At the highest concentrations tested of approximately 1 µM, these compounds were unable to fully inhibit the alkaline phosphatase activity stimulated by the D538G mutation and had no activity in cells containing the Y537S mutation. In contrast, both OP-1250 and fulvestrant were able to fully inhibit the alkaline phosphatase activity in cells containing these mutations. These observations suggest that tumors that become resistant to other estrogen therapies may remain sensitive to OP-1250.

Figure 10. Both OP-1250 and fulvestrant inhibit the activity of the ER containing mutations that commonly arise in breast cancer patients treated with other antiestrogen therapies.



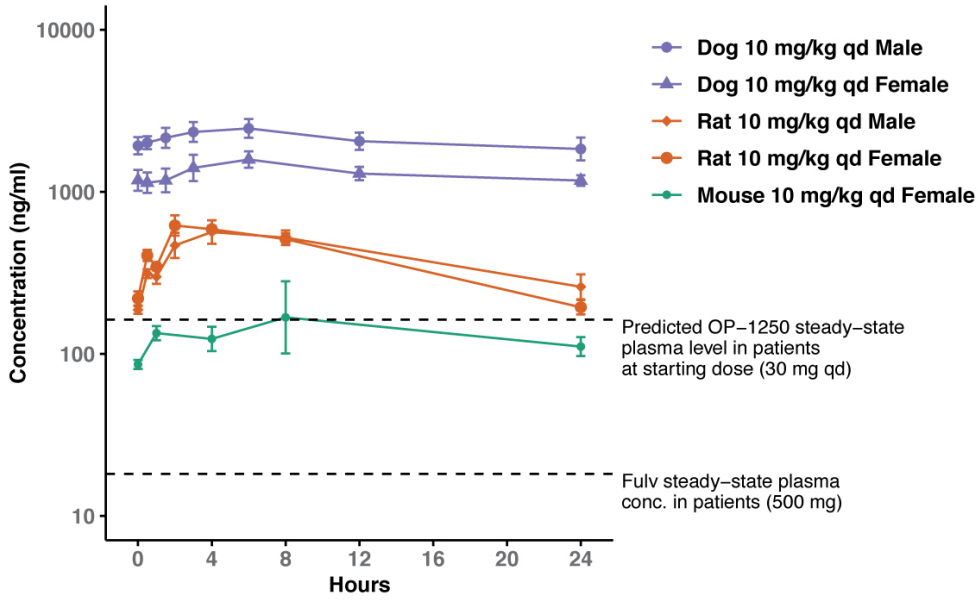
In vitro alkaline phosphatase, or AP, activity mediated by Y537S and D538G mutant ERα in an endometrial cell line. AP activity was assayed by treating transiently transfected Ishikawa cells with ligands in E2-depleted media for 3 days. Absorbance was read after incubation with a chromogenic substrate for AP. Shown are mean values normalized to vehicle, along with SEM from triplicate wells. The line labeled "endogenous" represents the mean AP activity of cells transfected with an empty vector, indicating the AP activity of the endogenous receptor. ARN-810, also known as GDC-0810, has been discontinued by Genentech.

Orally available, once daily dose

In animal studies, OP-1250 has demonstrated high oral availability with favorable exposure in four model species: mouse, rat, dog, and cynomolgus monkey; with a half-life supportive of once daily dosing in humans. Repeat daily dosing in these studies demonstrated that at steady-state the plasma levels of OP-1250 were relatively constant through the entire 24-hour period with little peak to trough variation. We believe that oral dosing of OP-1250 has the potential to achieve much higher drug levels as compared to fulvestrant administration

which requires two intramuscular injections every four weeks. The profile of OP-1250 is consistent with daily oral dosing in humans and we believe that we will be able to achieve targeted drug exposure levels with a once daily dose.

Figure 11. Steady state drug levels of OP-1250 following once daily dosing showed high plasma levels throughout the entire day

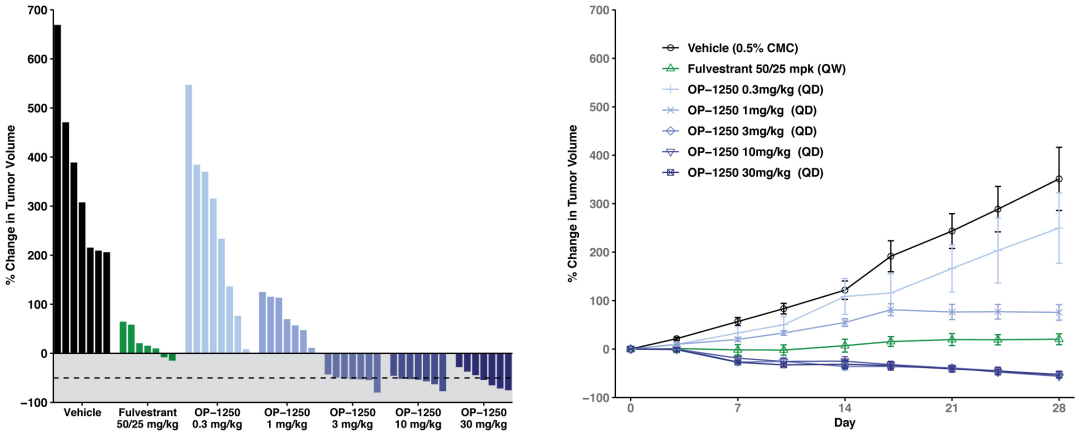


OP-1250 was dosed daily orally by gavage in the mouse rat and dog. After multi-day dosing, plasma levels were measured over the 24 hours following the last dose. Plasma levels were high, reached steady state, and showed allometric scaling.

Potent tumor shrinkage in nonclinical models

OP-1250 shrank or eliminated tumors in a wide variety of xenograft models including in an ovariectomized mouse breast cancer model designed to mimic the endocrine environment of post-menopausal women using HCI-013EI, an estrogen-independent patient-derived xenograft model containing a Y537S mutation. In this model, tumor growth occurred even in the absence of estrogen production due to the constitutive or always-on activity of the Y537S mutant ER protein. At daily oral doses of 3 mg/kg and higher, dosing with OP-1250 led to tumor reductions in all treated mice. In contrast, fulvestrant led to a detectable reduction in only two of the seven treated mice.

Figure 12. At daily oral doses of 3 mg/kg and above, treatment with OP-1250 led to tumor shrinkage in all treated mice in an HCI-013EI patient-derived xenograft model

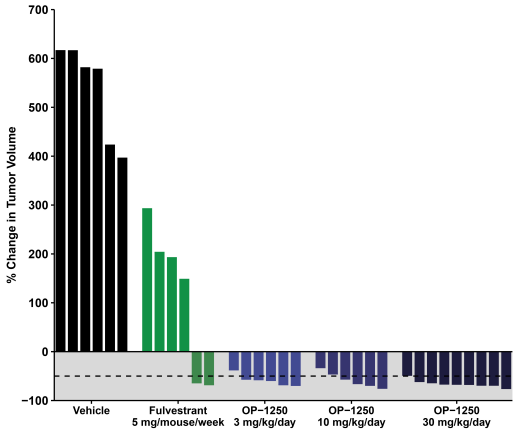


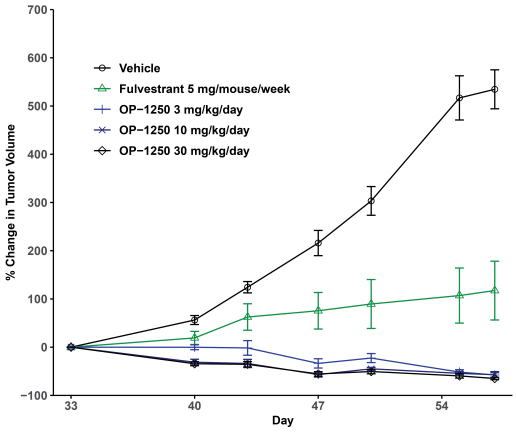
Change in tumor volume of HCI-013EI patient-derived tumors, carrying the Y537S mutation in the ER and adapted to grow without estrogen, implanted in the mammary fat pad of non-obese diabetic, or NOD/SCID ovariectomized mice. Mice were treated with oral OP-1250 at the dose indicated, or with subcutaneous fulvestrant (Faslodex preparation). Upper panel shows tumor size of each tumor measured with calipers at termination. Lower panel shows mean tumor size of each treatment group of 8 over the course of the study.

Daily oral dosing with OP-1250 led to tumor shrinkage in multiple xenograft models in mice with intact ovaries. These models included the HCC1500 cell line, which have wild-type ER and the ST941 and HCI-013 patient-derived xenograft models, both of which contain ERs that have the Y537S mutation. Similar to what was seen in the ovariectomized mouse model, OP-1250 demonstrated more potent antitumor activity than fulvestrant, which failed to consistently shrink tumors in any of these models.

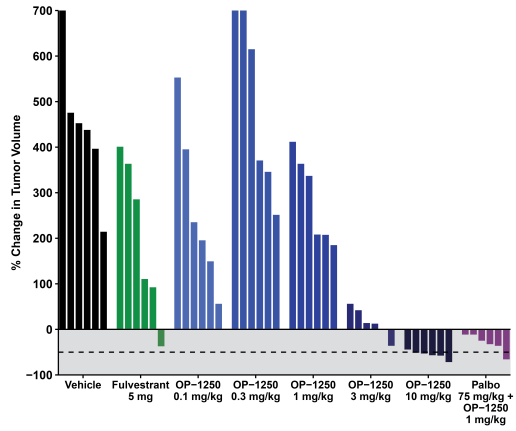
Figure 13. OP-1250 led to tumor shrinkage in multiple breast cancer xenograft models in mice including HCC1500, which contain wild-type ER, and ST941 and HCI-013, which contain the Y537S mutation in ER

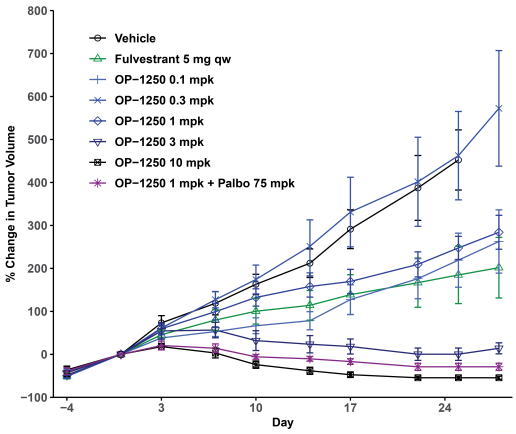
HCC1500



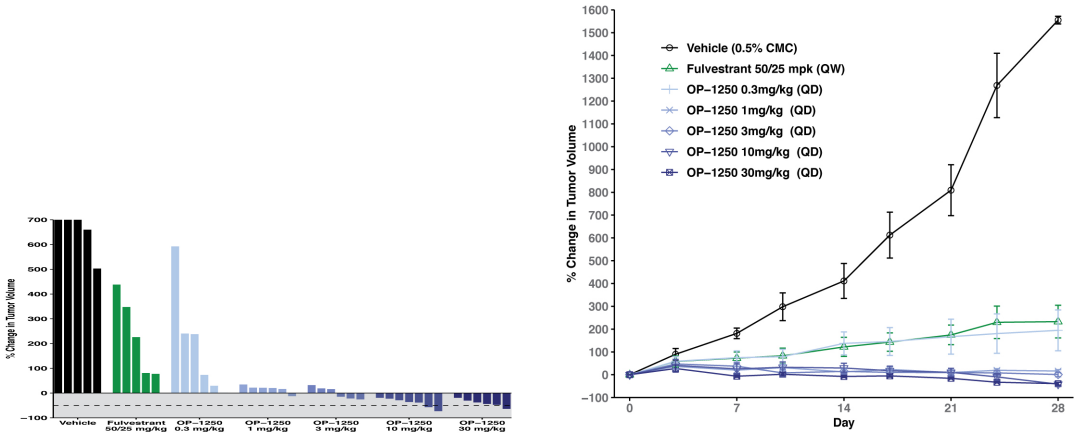


ST941





HCI-013



Change in tumor volume of various human xenograft tumors implanted in the mammary fat pad of ovary intact immunodeficient mice supplemented with estrogen releasing pellets and treated with the indicated dose of oral OP-1250, oral OP-1250 plus oral palbociclib, or subcutaneous fulvestrant (Faslodex preparation). Left panel of Figure 13 shows tumor size of each tumor measured with calipers at termination. Right panel shows mean tumor size of each treatment group of 8 over the course of the study. HCC1500, wild type ER cell line implanted in NSG mice; ST941 patient derived xenograft, or PDX, model with Y537S ER in JAX nude mice; HCI-013 PDX model with Y537S ER in NOD/SCID mice.

Drug accumulation in tumors

We observed that OP-1250 was consistently more effective in shrinking tumors in xenograft models than fulvestrant, despite the roughly equal potency of OP-1250 and fulvestrant in cell culture assays in which the drug is added directly to the cells. Detailed analyses of the tissue distribution of these two molecules identified that OP-1250 became concentrated in tumors many-fold greater as compared to plasma. By contrast, the tumor-to-plasma ratio for fulvestrant was 2 to 3.

Figure 14. Levels of OP-1250 were many-fold higher in tumors compared to those in plasma

Treatment	Dose (mg/kg)	Plasma (ng/mL)	Tumor (ng/g) (assuming density of 1g/mL)	Tumor to Plasma Ratio
OP-1250	0.3	1	11.5	12.84
OP-1250	1	10	106	10.8
OP-1250	3	54	1,463	27.0
OP-1250	10	344	13,610	39.5
OP-1250	30	1,226	55,184	45.0
Fulvestrant	50/25	69	175	2.6

OP-1250 was dosed daily orally by gavage in the mouse. Plasma levels were measured by high performance liquid chromatography, or HPLC. Tumors were removed surgically, weighed, macerated, and extracted to determine the concentration of OP-1250.

Brain penetration

There remains an unmet medical need in the treatment of patients with metastatic ER+/HER2- breast cancer that has spread to the brain. The challenges in treating brain metastasis are multifactorial and likely include the presence of resistance mutations and the inability to achieve efficacious levels of effective drugs in brain tissue. In mice, we found that OP-1250 reached drug levels in the brain as high as 50% greater than in plasma. Combined

with the ability to achieve higher drug levels with OP-1250, due to its improved PK properties, than fulvestrant, we found that we could obtain brain exposure to concentrations of OP-1250 that were greater than 30 times that of fulvestrant.

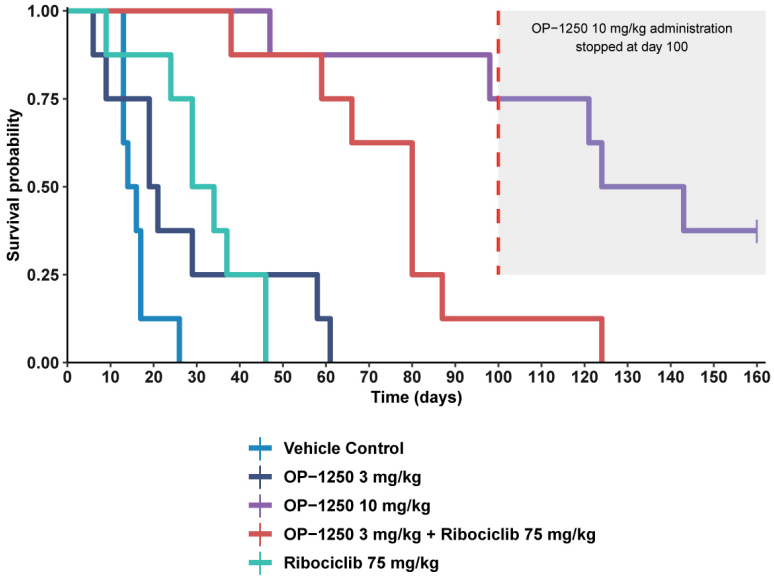
Figure 15. OP-1250 demonstrated robust CNS penetration in the mouse brain

Treatment	Dose (mg/kg)	Brain Concentration (ng/g)	Plasma Concentration (ng/mL)	Brain to Plasma Ratio
OP-1250	1	5	10	0.4
OP-1250	3	45	54	0.8
OP-1250	10	499	344	1.4
OP-1250	30	1920	1,226	1.6
Fulvestrant	50/25	60	69	0.9

OP-1250 was dosed daily orally by gavage in the mouse. Plasma levels were measured by HPLC. Cranial tissue samples removed surgically, weighed, macerated, and extracted to determine the concentration of OP-1250.

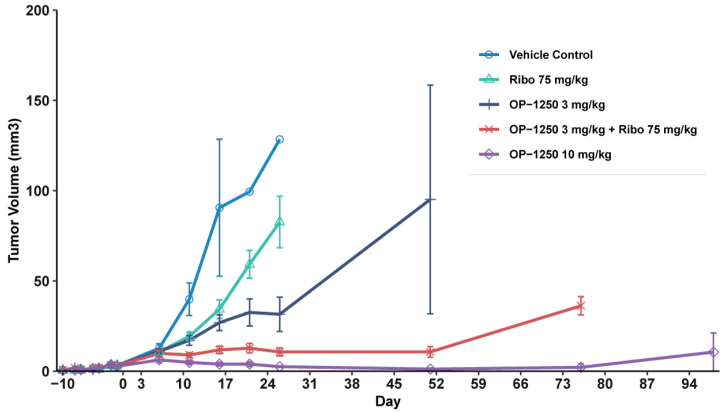
OP-1250 was effective in an intracranial xenograft brain metastasis model, in which ST941 tumor cells were implanted directly into the brain by stereotactic surgery. Tumors were stimulated with estrogen and allowed to grow for two or three weeks and their presence in the brain confirmed by MRI. The mice were then treated with one of the following: 3 mg/kg OP-1250; 10 mg/kg OP-1250; 75 mg/kg ribociclib, a CDK4/6 inhibitor known to cross the blood brain barrier; a combination of 3 mg/kg OP-1250 and 75 mg/kg ribociclib; or vehicle control. Mice were treated once daily for up to 100 days and followed for tumor size with MRI and survival. Monotherapy with 3 mg/kg OP-1250, or 75 mg/kg ribociclib, had small effects on survival, but the combination of both compounds increased survival five-fold from 15 to 80 days compared to vehicle control. In further contrast, mice treated with 10 mg/kg OP-1250 did not reach median survival at 100 days. No detectable tumors were found in six of the seven then surviving mice after 80 days, and six of eight mice were still alive after 100 days. Treatment was stopped at 100 days and the survival of the mice was followed. In this high dose, OP-1250 group median survival was reached at 125 days, despite suspension of therapy at day 100. At the conclusion of the experiment at day 160, two of the three surviving mice had no detectable brain tumor and the third had a slowly growing tumor. We believe that the ability of OP-1250 to eradicate brain metastasis in mice demonstrates the potential of OP-1250 to advance the treatment of patients with breast cancer with brain metastases.

Figure 16. Treatment with 10 mg/kg OP-1250 led to long-term survival in a xenograft model of breast cancer brain metastases



The figure above highlights an experiment in an intracranial breast cancer brain metastases xenograft study. Endpoints were tumor volume and survival. Shown is a Kaplan-Meier plot showing the percentage of surviving mice in each group over time. Tick marks indicate censored data reflecting that mice were enrolled on different days. Dashed red line shows cessation of treatment in OP-1250 10 mg/kg group.

Figure 17: Treatment with 10 mg/kg OP-1250 led to tumor shrinkage in a xenograft model of breast cancer brain metastases

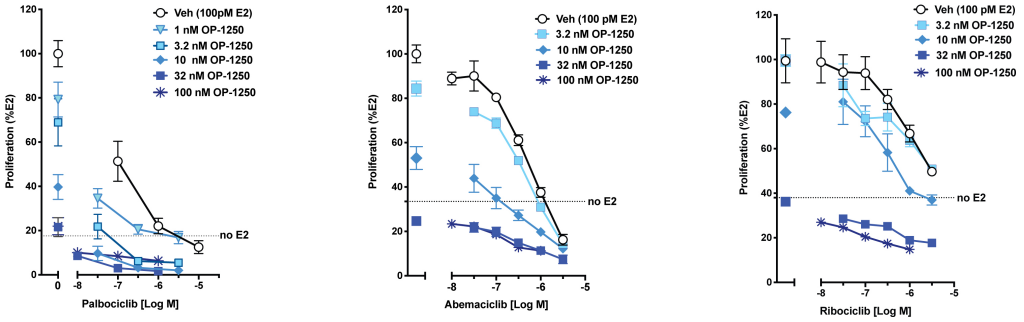


ST941 PDX material was stereotactically implanted directly into the brains of nude mice. Tumor volumes were followed and confirmed via MRI prior to inclusion in study. Drugs were administered for up to 100 days and tumor growth was followed via MRI. Daily oral administration of OP-1250 slowed tumor growth in the ST941 brain metastases model at 3 mg/kg, and shrunk tumors at 10 mg/kg. Ribociclib (ribo) at 75 mg/kg also slowed tumor growth but to a lesser degree than did OP-1250 at 3 mg/kg. The combination of 3 mg/kg OP-1250 and 75 mg/kg ribociclib substantially slowed tumor growth, to a much greater degree than 3 mg/kg OP-1250 or 75 mg/kg alone, but did not shrink tumors as OP-1250 as 10 mg/kg OP-1250 did.

Combinations with other breast cancer therapies

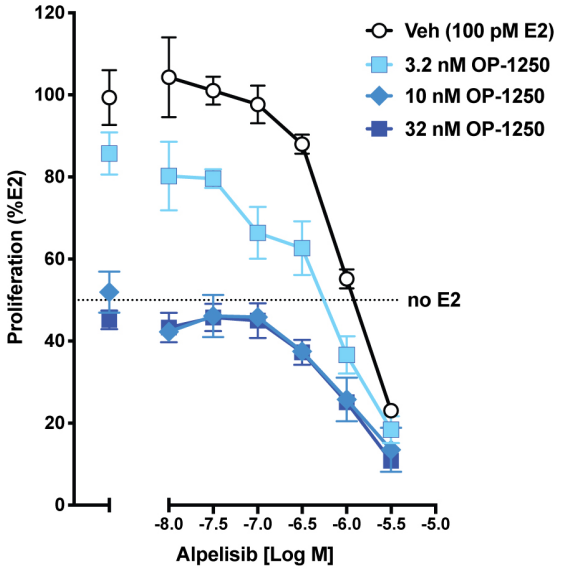
As in most other solid tumors, effective antitumor activity often requires the use of combination therapy. In the case of ER+ breast cancer, for example, activation of the CDK4/6 pathway is associated with resistance to fulvestrant and CDK4/6 inhibitors are routinely used in combination with fulvestrant. We observed that OP-1250 in combination with three different CDK4/6 inhibitors resulted in increased inhibition of MCF-7 cell proliferation as did OP-1250 in combination with the PI3Kα inhibitor alpelisib in T47D cells.

Figure 18. The combination of OP-1250 and CDK4/6 inhibitors resulted in potent anti-proliferative activity in MCF-7 cells



In vitro cell proliferation experiment measuring DNA content after 7-day treatment of MCF-7 breast cancer cells with ligands in the presence of 100 pM E2. Shown are mean values normalized to vehicle (+E2), along with SEM from triplicate wells.

Figure 19. The combination of OP-1250 and PI3Kα inhibitors resulted in potent anti-proliferative activity in T47D cells



In vitro cell proliferation experiment measuring DNA content after 6-day treatment of T47D breast cancer cells with ligands in the presence of 100 pM E2. Shown are increasing concentrations of alpelisib with three different concentrations of OP-1250, mean values normalized to vehicle (+E2), and SEM from triplicate wells.

Summary of nonclinical properties

We believe OP-1250's oral formulation and dual mechanism of action directly address the limitations of current endocrine therapies, such as fulvestrant and tamoxifen, and position OP-1250 as a potential endocrine therapy of choice for the treatment of ER+ breast cancers. We have demonstrated in nonclinical studies that OP-1250 functions both as a CERAN and a SERD, but is distinguished from fulvestrant in several noteworthy ways, including:

- *OP-1250 is orally bioavailable while fulvestrant is a highly insoluble compound that must be administered monthly by intramuscular injection into the buttocks;*
- *OP-1250 has favorable biodistribution properties leading to higher drug concentrations in the plasma and tumor than those achieved with fulvestrant, as shown in a head-to-head mouse xenograft study; and*

- *OP-1250 has demonstrated the ability to shrink tumors in head-to-head nonclinical studies with fulvestrant, in contrast to fulvestrant, which has only been shown to inhibit tumor growth.*

We believe OP-1250 has the potential to improve clinical outcomes for patients with metastatic breast cancer, initially for patients who have previously received endocrine therapy, as well as those who are treatment naïve in the metastatic setting. Additionally, given the differentiated product profile, we believe that OP-1250 has the potential to advance into the adjuvant setting for early-stage ER+ breast cancer.

Clinical development plan for OP-1250 and additional clinical opportunities

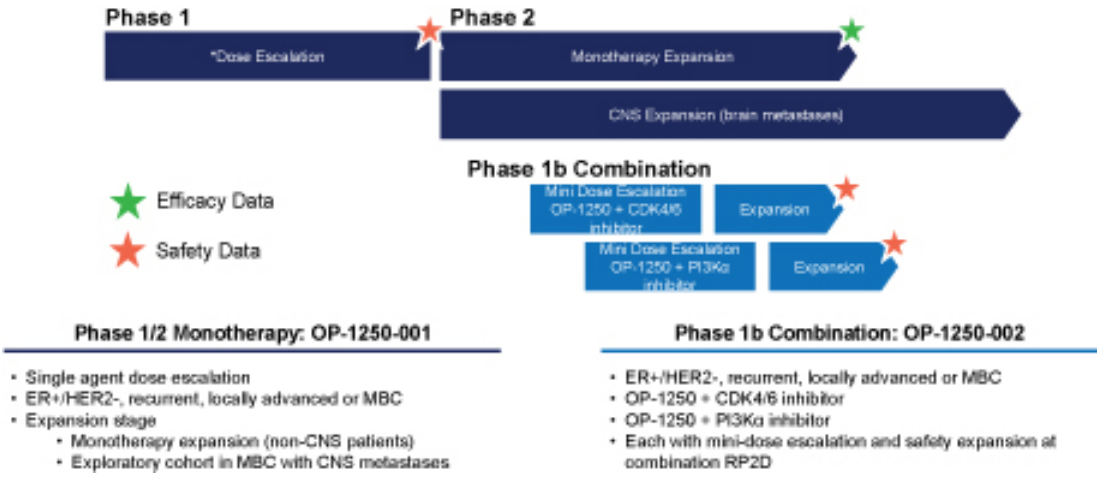
In August 2020, we initiated enrollment in our Phase 1/2 open label, multi-center clinical trial of OP-1250, OP-1250-001, in patients, both women and men, with recurrent, locally advanced or metastatic ER+/HER2- breast cancer. The Phase 1 portion of this trial consists of monotherapy dose-escalation cohorts of three to six patients receiving oral daily doses of OP-1250. The primary objectives of this portion of the trial are to assess safety, tolerability, PK, pharmacodynamics and the determination of the MTD and/or the RP2D. We expect to report initial data from the Phase 1 portion of this trial in the second half of 2021.

After determining the MTD or RP2D for OP-1250 as monotherapy, we expect to initiate enrollment in the Phase 2 dose expansion portion of the trial to assess preliminary anti-tumor efficacy of OP-1250 as assessed by response rate and other clinical endpoints including safety, tolerability and PK. One cohort will enroll metastatic breast cancer patients whose disease has progressed following at least one anti-estrogen therapy in the advanced setting. A second cohort is exploratory and will enroll metastatic breast cancer patients diagnosed with brain metastases. Patients will be treated until progression of disease or unacceptable toxicity. Additionally, ESR1 status and relevant mutations will be evaluated from cell free DNA at various time points throughout the trial in order to assess outcomes in patients with both wild-type and mutant genes.

As of October 23, 2020, the first dose cohort, consisting of four patients, has completed enrollment and the initial 28 day dose limiting toxicity assessment period, and the second dose cohort is enrolling patients. Preliminary PK data from the first dose cohort is consistent with nonclinical modeling of our Phase 1 starting dose.

We currently anticipate enrolling up to 94 patients in the OP-1250-001 trial. We expect such trial to generate safety, PK, response and other data in patients with and without ESR1 mutations, and data in patients that are both pre and post-menopausal. The design of the trial allows the potential to expand our cohorts to include additional patient subsets as the trial design and data help to identify those patients most likely to benefit. A robust monotherapy response rate along with a clinically meaningful duration of response would enable us to move directly to a randomized pivotal trial evaluating OP-1250 versus fulvestrant in either an unselected population, a selected subset (patients with ESR1 mutations) or both.

Figure 20. Designs of the Phase 1/2 OP-1250-001 trial and Phase 1b OP-1250-002 for OP-1250



After the RP2D dose is identified in the current OP-1250-001 trial, OP-1250 will be evaluated in combination with both a CDK4/6 inhibitor, and a PI3Kα inhibitor in patients with a PIK3CA mutation. Each combination will be evaluated in an abbreviated dose escalation starting one to two dose levels below the RP2D of OP-1250 identified in the Phase 1 portion of the trial followed by a small expansion cohort to further evaluate the safety of each of the two combinations. Assuming that each combination is well tolerated, and that the monotherapy efficacy data from the Phase 1/2 trial is robust, we could move each combination into a registration directed pivotal trial.

Historically, treatment for pre-menopausal women with ER+ breast cancer was limited to tamoxifen given the dual source of estrogen in women with functioning ovaries. Today, some clinicians will treat pre-menopausal women with luteinizing hormone-releasing hormone, or LHRH, agonists to suppress ovarian function in combination with drugs such as AIs or fulvestrant. Given OP-1250's potency, and our data in nonclinical models of pre-menopausal animals, we intend to further study OP-1250 in pre-menopausal women without the use of LHRH agonists once preliminary data from the OP-1250-001 trial is obtained.

While all populations described above are in patients with ER+/HER2- breast cancer, we believe that there is an opportunity for us to study OP-1250 in patients with ER+/HER2+ breast cancer, which represents approximately 11% of breast cancer patients and more than 50% of the patients with HER2+ breast cancer. In particular, up to 50% of patients with metastatic HER2+ breast cancer develop CNS disease. Combining OP-1250 with HER2 targeted agents may represent an opportunity to improve upon recent advancements in the treatment of CNS disease in patients that express both ER and HER2.

In addition to breast cancer, we intend to explore the use of OP-1250 in various gynecological malignancies, beginning with endometrial cancer. Approximately 80% of endometrial tumors are "endometriod" in nature and these tumors are driven by estrogen.

While our initial trials are focused on treating breast cancer patients with metastatic disease, we believe that if OP-1250 is determined to be safe and effective in this population, there is potential for it to be used in earlier stage disease. Based on our extensive nonclinical studies, including certain head-to-head studies, we believe that OP-1250 could have superior PK properties and improved clinical outcomes than fulvestrant. If proven in the clinic, we believe that OP-1250 has the potential to not only replace fulvestrant but to become the endocrine treatment of choice for the treatment of both advanced/metastatic ER+ breast cancer as well as ultimately in early-stage ER+ breast cancer in the adjuvant setting.

Clinical trial collaboration and supply agreement with Novartis

In July 2020, we entered into a non-exclusive Clinical Collaboration and Supply Agreement, or the Novartis Agreement, with Novartis. The collaboration is focused on the evaluation of the safety, tolerability and efficacy of OP- 1250 in combination with Novartis' proprietary CDK4/6 inhibitor Kisqali® (ribociclib) and/or Novartis' proprietary phosphatidylinositol 3-kinase inhibitor Piqray® (alpelisib), or collectively the Novartis Study Drugs, as part of our planned Phase 1b clinical trial of OP-1250 in patients with metastatic ER+ breast cancer. We will be responsible for the conduct of the clinical trials for the combined therapies in accordance with a mutually agreed development plan. As part of the collaboration, the parties granted to each other a non-exclusive, royalty-free license under certain of the parties' respective background patent rights and other technology to use the parties' respective study drugs in research and development, solely to the extent reasonably needed for the other party's activities in the collaboration. All inventions and data developed in the performance of the clinical trials for the combined therapies (other than those specific to each component study drug), will be jointly owned by the parties.

We are responsible for manufacturing, packaging and labeling OP-1250, and for packaging and labeling all drugs used in the clinical trials for the combined therapies (other than the Novartis Study Drugs). Novartis is responsible for manufacturing and delivering to us the Novartis Study Drugs in such quantities as reasonably needed for the clinical trials for the combined therapies. In accordance with an agreed budget, Novartis will reimburse us for a majority of the direct outside costs, but no more than an amount in the low single digit millions

of U.S. dollars, that we incur related to conducting the activities under the agreed development plan in conducting the clinical trials for the combined therapies.

The Novartis Agreement will terminate upon completion of all activities outlined in the development plan and the relevant protocols. Either party may terminate the Novartis Agreement for the uncured material breach or insolvency of the other party, if it reasonably deems it necessary in order to protect the safety, health or welfare of subjects enrolled in the clinical trials for the combined therapies due to the existence of a material safety issue, or in certain circumstances for an unresolved clinical hold with respect to either the Novartis Study Drugs or OP-1250. In addition, Novartis may terminate the Novartis Agreement if certain disputes between the parties are not resolved after following the applicable dispute resolution procedures, and we may terminate the Novartis Agreement in the event we terminate all clinical trials of the combined therapies other than due to a material safety issue or upon a clinical hold.

The Novartis Agreement does not grant any right of first negotiation to participate in future clinical trials, and each of the parties retains all rights and ability to evaluate their respective compounds in any studies or clinical trials, either as a monotherapy or in combination with any other product or compound, in any therapeutic area. The parties retain their independent rights to commercialize their respective therapies both alone or with other parties.

Clinical trial agreement with Pfizer

In November 2020, we entered into a non-exclusive clinical trial agreement with Pfizer Inc., or Pfizer, to evaluate the safety and tolerability of OP-1250 in combination with Pfizer's proprietary CDK4/6 inhibitor IBRANCE® (palbociclib) in patients with recurrent, locally advanced or metastatic ER+, HER2- breast cancer in a clinical trial. Under the terms of the non-exclusive agreement, we will be responsible for conducting the clinical trial for the combined therapies and Pfizer is responsible for supplying IBRANCE® to us at no cost to us.

Intellectual property

Our success depends, in part, on our ability to obtain, maintain and protect our intellectual property and other proprietary rights for OP-1250 and any future product candidates and other discoveries, inventions, trade secrets and know-how that are critical to our business operations. Our success also depends in part on our ability to operate without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of others, and in part, on our ability to prevent others from infringing, misappropriating or otherwise violating our intellectual property and proprietary rights. A comprehensive discussion on risks relating to intellectual property is provided under the section titled "Risk Factors—Risks Related to Our Intellectual Property."

Intellectual property rights relevant to pharmaceutical companies typically include a combination of patent rights, regulatory exclusivities, trademark rights, and trade secret protection. Our success depends, in part, on our ability to secure and enforce each of these types of intellectual property rights.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of biotechnology has emerged in the United States and in Europe, among other countries. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, importing or otherwise commercializing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending and enforcing patent claims that cover our technology, inventions, and improvements. Regardless of the coverage we seek under our existing patent applications, there is always a risk that an alteration to the product or process may provide sufficient basis for a competitor to avoid infringement claims. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued and courts can reinterpret patent scope after issuance. Moreover, many jurisdictions, including the United

States, permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims.

An issued patent provides its owner (or possibly its licensee) with a right to exclude others from making, using or selling that which is claimed in the patent, for a specified period of time (the "term" of the patent), in the jurisdiction in which the patent is issued. In the United States, and in many other countries, utility patents have a presumptive term of 20 years from their effective filing date (which is the earliest non-provisional filing date to which the patent claims priority). However, many jurisdictions, including the United States, require the payment of periodic annuities or maintenance fees in order for patents to remain in force for the full 20-year term. The United States also has provisions that require a patent term to be shortened if its claims are too similar to another patent owned by the same party that has a shorter term. The term of a patent, and the protection it affords, is therefore limited and once the patent term of our issued patents has expired, we may face competition. Because of the extensive time required for clinical development and regulatory review of the drugs we develop, it is possible that, before OP-1250 or any future product candidates we may develop 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.

The United States and certain other jurisdictions also have provisions that permit extension of patent term for patents that claim a drug or drug product, or its approved use, if the patent was issued before clinical trials and were completed and regulatory approval secured, so long as certain specific requirements were satisfied. In the United States, such extension associated with regulatory approval is called a Patent Term Extension, or PTE, and it is limited to a maximum of five years, or less if the extended patent term would exceed 14 years after the date of regulatory approval. Only one patent can receive regulatory extension (*e.g.,* PTE) per product approval.

The United States also offers a different form of patent term extension, known as Patent Term Adjustment, or PTA, whereby a particular patent's term is automatically extended beyond the 20-year date if the United States Patent and Trademark Office, or the USPTO, caused delay during its examination; however, potentially available PTA is reduced by any amount of any delay caused by the patent applicant. We may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. There can be no assurance that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents.

A provisional patent application can establish a priority date for a patent, but only if certain deadlines and procedures are met. Specifically, a non-provisional application must be filed within 12 months of the provisional filing date, and such non-provisional filing must be made by an applicant who has properly documented its right to claim priority. Furthermore, if any changes are made to the application between the provisional and the non-provisional filings, the changed material may not be entitled to the priority filing date. Still further, in the biopharmaceutical industry, it is common for applicants to file a so-called "international" patent application under the Patent Cooperation Treaty, or PCT, as a non-provisional filing. Such an international application, often referred to as a "PCT application," like a provisional application, cannot itself issue as a patent but rather preserves the applicant's right to pursue patent filings in individual countries, which patent filings are referred to as "national applications" or "national phase filings" and can claim the benefit of priority to the prior PCT application (which may in turn claim priority to the prior provisional filing). For most jurisdictions, national phase applications claiming priority to a PCT application must be filed within 30 to 32 months of the PCT's earliest priority date. If we fail to meet the deadline for filing non-provisional or national phase applications, or fail to complete all procedural requirements associated with such filings, we may lose our right to claim priority. Moreover, even if we comply with all deadlines and requirements, we may not be able to issue patents in relevant jurisdictions, and furthermore cannot predict whether any patents that might issue will provide us with any competitive advantage.

As of November 2, 2020, we own two issued patents in the United States and one granted patent in Japan relating to OP-1250. These patents claim the OP-1250 compound, pharmaceutical compositions that include OP-1250, and certain methods of using OP-1250, including in treatment which may involve combination therapy; the 20-year term for these patents expires in 2036. Neither of the U.S. patents was awarded any PTA and it is uncertain

whether any PTE will be available, and if so, how much. A related U.S. application remains pending, and applications are also pending in 17 ex-U.S. jurisdictions, including certain major market countries such as Australia, Canada, China, Europe and Japan. Two additional unpublished applications are pending, relating to certain dosing regimens or treatment of particular cancers or patient populations, and one of these is at the PCT stage, and one is a U.S. provisional application.

Certain patents related to OP-1250 may be eligible for PTE in certain jurisdictions, including the United States and Europe, upon approval of a commercial use of the corresponding product by a regulatory agency in the jurisdiction where the patent was granted. However, there can be no assurance that we will receive or benefit from any PTE with respect to such patents.

In addition to patent term extension regulatory exclusivities, pharmaceutical marketing approval agencies such as the FDA and the European Medicines Agency, or the EMA, offer certain data exclusivities for first-approved products with a new chemical entity, or NCE, exclusivity, and/or for approvals related to orphan indications, or Orphan Drug designation, and/or pediatric approvals, or Pediatric Exclusivity.

Furthermore, as OP-1250 has not previously been approved in the United States for any indication, OP-1250 may be eligible for five years of NCE exclusivity upon its first approval. Should that approval be for an orphan indication for which we have received Orphan Drug designation, the NCE and Orphan Drug exclusivity would run concurrently.

With respect to our owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any current patents or any patents that may be granted to us in the future will be commercially useful in protecting OP-1250 or any future product candidates and the methods used to manufacture them. Moreover, any issued patents and those that may issue in the future may not guarantee us the right to practice our technology in relation to the commercialization of OP-1250 or any future product candidates. Any patents and those that may issue in the future may be challenged, narrowed, circumvented or invalidated, which could limit our ability to stop competitors from marketing related product candidates or limit the length of the term of patent protection that we may have for OP-1250 or any future product candidates. In addition, the rights granted under any issued patents may not provide us with complete protection or competitive advantages against competitors with similar products to ours. For information regarding risks related to intellectual property, see the section titled “Risk Factors —Risks Related to Our Intellectual Property.”

We have also applied to register the “Olema,” “Olema Oncology,” and “Olema Therapeutics” trademarks with the USPTO. We do not currently own any U.S. registered trademarks for our brand or trade names. Our trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

In addition to patent, regulatory exclusivity, and trademark, we rely on trade secret and know-how protection to secure our proprietary position around our chemistry, technology and other discoveries and inventions that we consider important to our business.

We also seek to protect our intellectual property, including our trade secrets and know-how, in part by entering into confidentiality agreements with companies with whom we share proprietary and confidential information in

the course of business discussions, and by having confidentiality terms in our agreements with our employees, consultants, scientific advisors, clinical investigators and other contractors and also by requiring our employees, commercial contractors, and certain consultants and investigators, to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them while in our employ. However, trade secrets and know-how can be difficult to protect. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes or that these agreements will afford us adequate protection of our intellectual property and proprietary rights. 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. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. For information regarding risks related to intellectual property, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Sales and marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We intend to build a commercial infrastructure to support sales of any approved products. We intend to continue evaluating opportunities to work with partners that enhance our capabilities with respect to the development and commercialization of OP-1250. In addition, we intend to commercialize our product candidates, if approved, in key markets either alone or with partners in order to maximize the worldwide commercial potential of our programs.

Manufacturing

We currently do not own or operate any manufacturing facilities. We rely, and expect to continue to rely for the foreseeable future, on third-party contract manufacturing organizations, or CMOs, to produce OP-1250 for nonclinical and clinical testing, as well as for commercial manufacture if OP-1250 receives marketing approval. We require that our CMOs produce bulk drug substances and finished drug products in accordance with current Good Manufacturing Practices, or cGMPs, and all other applicable laws and regulations. We maintain agreements with our manufacturers that include confidentiality and intellectual property provisions to protect our proprietary rights related to OP-1250.

We have engaged CMOs to manufacture and package OP-1250 for nonclinical and clinical use. Additional CMOs are used to label and distribute OP-1250 for clinical use. We obtain our supplies from these CMOs on a purchase order basis and do not have long-term supply arrangements in place. Although we do not currently have contractual arrangements in place for redundant supply for OP-1250, it is our goal to identify and contract with at least two manufacturers for active pharmaceutical ingredient and two manufacturers for drug product. More broadly, for OP-1250 and any other product candidates we may develop, we intend to identify and qualify additional manufacturers to provide the active pharmaceutical ingredient and fill-and-finish services prior to seeking regulatory approval.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid technological advancement, significant competition and an emphasis on intellectual property. We face potential competition from many different sources, including major and specialty pharmaceutical and biotechnology companies, academic research institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with current therapies and new therapies that may become available in the future.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, nonclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology 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 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 less expensive than any products we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in competitors establishing a strong market position before we are able to enter the market. We believe that the key competitive factors affecting the success of any of our product candidates, if approved, will include efficacy, combinability, safety profile, convenience, cost, level of promotional activity devoted to them and intellectual property protection.

If the product candidates for our priority programs are approved for the indications we are currently targeting, they will compete with the products discussed below. Furthermore, it is possible that other companies are also engaged in discovery or nonclinical development of product candidates for the same indications. These competitors, if successful in clinical development, may achieve regulatory approval and market adoption in advance of our product candidates, constraining our ability to gain significant market share for such product candidates. In addition, our product candidates, if approved, will complete with multiple approved products or products that may be approved for future indications for which we develop such product candidate.

There are several currently marketed drugs and product candidates currently in development for the treatment of ER+ breast cancer that may compete with OP-1250 if approved, including: certain CERAN therapies, such as RG6171 being developed by Roche Holding AG/Genentech, Inc., fulvestrant, marketed as Faslodex® by AstraZeneca PLC, or any generic equivalents of Faslodex® that may be developed, AZD9833 being developed by AstraZeneca PLC, SAR439859 being developed by Sanofi S.A. and LY3484356 being developed by Eli Lilly and Co.; companies that develop or produce SERD or non-CERAN SERD therapies, such as ZN-c5 being developed by Zentalis Pharmaceuticals, Inc., elacestrant being developed by Radius Health, Inc., ARV-471 being developed by Arvinas, Inc., rintodestrant (G1T48) being developed by G1 Therapeutics, Inc. and H3B-6545 being developed by H3 Biomedicines, a subsidiary of Eisai Co., Ltd.

Government regulation and product approval

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation. Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products such as those we are developing. Any drug candidates that we develop must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects.

U.S. Drug development process

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could

include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory tests, nonclinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practices, or GLP, regulations and other applicable regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable regulations, including the FDA's current good clinical practice, or GCP, regulations to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an New Drug Application, or NDA, for a new drug;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA's current good manufacturing practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the nonclinical and/or clinical trial sites that generated the data in support of the NDA;
- satisfactory completion of an FDA advisory committee review, if applicable; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

Before testing any compounds with potential therapeutic value in humans, the drug candidate enters the nonclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies, to assess the characteristics and potential safety and activity of the drug candidate. The conduct of the nonclinical tests must comply with federal regulations and requirements including GLPs. The sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. Some nonclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance.

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

Clinical trials involve the administration of the drug candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control,

in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion, the side effects associated with increasing doses and if possible, to gain early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2*. The drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases or conditions and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall benefit/risk ratio of the product and provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of Phase 4 trials. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial.

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

U.S. Review and approval processes

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation. Unless otherwise required by regulation, the Pediatric Research Equity Act does not apply to any drug for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of “filing” of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a “filing” decision after it the application is submitted The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product’s identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products which 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 and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and typically follows the advisory committee’s recommendations.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical sites to assure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates

that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or (an) additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. For example, the FDA may require Phase 4 testing, which involves clinical trials designed to further assess a drug safety and effectiveness, and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also determine that a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

Orphan drug designation

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

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our product candidate is determined to be contained within the competitor’s product for the same indication or disease. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. Orphan drug status in the European Union has similar but not identical benefits in that jurisdiction.

Expedited development and review programs

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Unique to a fast track product, the FDA may consider for review

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

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy for a serious condition where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a serious condition compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

A sponsor may seek FDA designation of a drug candidate as a “breakthrough therapy” if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes intensive FDA interaction and guidance. If a drug is designated as breakthrough therapy, FDA will expedite the development and review of such drug. Breakthrough therapy designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, this designation may not provide a material commercial advantage.

Post-approval requirements

Any drug products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug’s approved labeling (known as “off-label use”), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long term stability of the drug product. We rely, and expect to

continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

U.S. Patent term restoration and marketing exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, may be eligible for limited PTE under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. As compensation for patent term lost during product development and the FDA regulatory review process, the Hatch-Waxman Amendments permit a patent restoration term, or PTE, which is limited to a maximum of five years, or less if the extended patent term would exceed 14 years after the date of the regulatory approval of the product. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug or drug product, or its approved use, is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of a patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. There can be no assurance that we will benefit from any PTE or favorable adjustment to the term of any of our patents.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended

for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of non-patent market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued “Written Request” for such a trial.

Other U.S. Healthcare laws and compliance requirements

Although we currently do not have any products on the market, we are and, upon approval and commercialization, will be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. In the United States, such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting, and provider transparency laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the Anti-Kickback Statute and the criminal healthcare fraud statutes (discussed below) was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, together with subsequent amendments and regulations, collectively, the ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below).

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product and for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-covered, uses.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) annually report information related to certain payments or other transfers of value made or distributed to physicians, certain other healthcare providers and teaching hospitals, certain ownership and investment interests held by these healthcare providers and their immediate family members.

We may also be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

We also are or will become subject to privacy laws in the jurisdictions in which we are established or in which we sell or market our products or run clinical trials. For example, in Europe we are subject to Regulation (EU) 2016/679, the General Data Protection Regulation, or GDPR, in relation to our collection, control, processing and other use of personal data (i.e. data relating to an identifiable living individual). We process personal data in relation to participants in our clinical trials in the European Economic Area, or EEA, including the health and medical information of these participants. The GDPR is directly applicable in each European Union Member State, however, it provides that European Union Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business.

The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of personal

data; defines pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. We are subject to the supervision of local data protection authorities in those European Union jurisdictions where we are established or otherwise subject to the GDPR. Fines for certain breaches of the GDPR are significant: up to the greater of €20 million or 4% of total global annual turnover. Further, following the withdrawal of the United Kingdom from the European Union on January 31, 2020, pursuant to the transitional arrangements agreed between the United Kingdom and the European Union, we will have to comply with the GDPR and separately the GDPR as implemented in the United Kingdom, each regime having the ability to fine up to the greater of €20 million/ £17 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, including how data transfers between European Union member states and the United Kingdom will be treated. These changes may lead to additional compliance costs and could increase our overall risk. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, or potential civil claims including class action type litigation.

In addition, the GDPR includes restrictions on cross-border data transfers. Certain aspects of cross-border data transfers under the GDPR are uncertain as the result of legal proceedings in the European Union, including a recent decision by the Court of Justice for the European Union that invalidated the EU-U.S. Privacy Shield and, to some extent, called into question the efficacy and legality of using standard contract clauses. This may increase the complexity of transferring personal data across borders. The GDPR will increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. We are also subject to European Union rules with respect to cross-border transfers of personal data out of the European Union and EEA. Recent legal developments in the European Union have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. On July 16, 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-US Privacy Shield Framework, or Privacy Shield, under which personal data could be transferred from the EEA to US entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy, subject to certain conditions, of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism), future regulatory guidance could result in changes to the use of standard contractual clauses. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, the vote in the United Kingdom in favor of exiting the European Union, referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. Specifically, while the Data Protection Act of 2018, which “implements” and complements the GDPR achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, aspects of data protection in the United Kingdom, such as the transfer of data from the EEA to the United Kingdom, remain uncertain. During the period of “transition” (i.e., until December 31, 2020), European Union law will continue to apply in the United Kingdom, including the GDPR, after which the GDPR will be converted into United Kingdom law. Beginning in 2021, the United Kingdom will be a “third country” under the GDPR.

In addition, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies’ data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA provides for civil penalties for violations, as

well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA became effective on January 1, 2020, and (a) allows enforcement by the California Attorney General, with fines set at $2,500 per violation (i.e., per person) or $7,500 per intentional violation and (b) authorizes private lawsuits to recover statutory damages for certain data breaches. In addition, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we would become subject if it is enacted. The CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Additionally, a new privacy law, the California Privacy Rights Act, or CPRA, recently was certified by the California Secretary of State to appear on the ballot for the November 3, 2020 election. If this initiative is approved by California voters, the CPRA would significantly modify the CCPA, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, track and report gifts, compensation and other remuneration made to physicians and other healthcare providers, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private “qui tam” actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. For information regarding risks related to these compliance requirements, see the section titled “Risk Factors—Risks Related to Regulatory Approval and Other Legal Compliance Matters.”

Pharmaceutical coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we or our collaborators obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we or our collaborators receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such drug products. In the United States, third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers and other organizations. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Such payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. We or our collaborators may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Nonetheless, our

product candidates may not be considered medically necessary or cost-effective. Moreover, the process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

If we elect to participate in certain governmental programs, we may be required to participate in discount and rebate programs, which may result in prices for our future products that will likely be lower than the prices we might otherwise obtain. For example, drug manufacturers participating under the Medicaid Drug Rebate Program must pay rebates on prescription drugs to state Medicaid programs. Under the Veterans Health Care Act, or VHCA, drug companies are required to offer certain drugs at a reduced price to a number of federal agencies, including the U.S. Department of Veterans Affairs and Department of Defense, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs, including Medicare and Medicaid. Recent legislative changes require that discounted prices be offered for certain U.S. Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA also requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations. If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

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

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other healthcare funding and applying new payment methodologies. For example, in March 2010, the ACA was enacted, which affected existing government healthcare programs and resulted in the development of new programs.

Among the Affordable Care Act's provisions of importance to the pharmaceutical industry, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some 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% of the average manufacturer price for most branded and generic drugs, respectively, and a cap on the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered 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, including individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. For example, the Tax Cuts and Jobs Act, or the Tax Act was enacted, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how this litigation and other efforts to repeal and replace the ACA will impact the ACA and our business.

Other legislative changes have also been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020 and extended the sequester by one year, through 2030. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which has resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. The Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to

support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. In addition, on March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. On July 24, 2020, President Trump announced four executive orders related to prescription drug pricing that attempt to implement several of the Administration’s proposals, including a policy that would tie Medicare Part B drug prices to international drug prices; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for plans, pharmacies, and pharmaceutical benefit managers; and one that reduces costs of insulin and epipens to patients of federally qualified health centers. While some of these and other measures may require additional authorization 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. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We anticipate that these new laws will result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products (if approved). In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition, and results of operations. For example, it is possible that additional governmental action is taken to address the COVID-19 pandemic.

The U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act of 1977, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Europe / rest of world government regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we or our potential collaborators obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial application, or CTA, must be submitted

to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under European Union regulatory systems, we must submit a marketing authorization application either under the so-called centralized or national authorization procedures.

Centralized procedure. The centralized procedure provides for the grant of a single marketing authorization following a favorable opinion by the EMA that is valid in all European Union member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions. The centralized procedure is optional for products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health.

National authorization procedures. There are also two other possible routes to authorize medicinal products in several European Union countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

- *Decentralized procedure*. Using the decentralized procedure, an applicant may apply for simultaneous authorizations in more than one European Union country of medicinal products that have not yet been authorized in any European Union Member State and that do not fall within the mandatory scope of the centralized procedure.
- *Mutual recognition procedure*. In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

The EMA grants orphan drug designation to promote the development of products that may offer therapeutic benefits for life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the European Union. In addition, orphan drug designation can be granted if the drug is intended for a life threatening, seriously debilitating or serious and chronic condition in the European Union and without incentives it is unlikely that sales of the drug in the European Union would be sufficient to justify developing the drug. Orphan drug designation is only available if there is no other satisfactory method approved in the European Union of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients. Orphan drug designation provides opportunities for free protocol assistance, fee reductions for access to the centralized regulatory procedures and ten years of market exclusivity following drug approval, which can be extended to 12 years if trials are conducted in accordance with an agreed-upon pediatric investigational plan. The exclusivity period may be reduced to six years if the designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Employees and human capital resources

As of November 16, 2020, we had 22 employees, 21 of whom were full-time, consisting of clinical, research, operations, regulatory, finance and business development personnel. Ten of our employees hold Ph.D. or M.D. degrees. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

Facilities

Our corporate headquarters are located in San Francisco, California, where we lease approximately 3,500 square feet of office space pursuant to a lease agreement which commenced on September 1, 2020 and expires on August 31, 2022. We believe that these existing facilities will be adequate for our near-term needs. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

Legal proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Management

Executive officers, directors and key consultant

The following table sets forth information regarding our executive officers, directors and key consultant as of November 16, 2020.

Name	Age	Position
Executive Officers:		
Sean Bohen, M.D., Ph.D.	54	President, Chief Executive Officer and Director
Cyrus L. Harmon, Ph.D.	50	Chief Technology Officer and Director
Peter J. Kushner, Ph.D.	82	Chief Scientific Officer
David C. Myles, Ph.D.	58	Chief Development Officer
Shane Kovacs	47	Chief Operating and Financial Officer
Kinney Horn	46	Chief Business Officer
John B. Moriarty, Jr., J.D.	53	Executive Vice President, Chief Legal Officer and Corporate Secretary
Non-Employee Directors:		
Ian Clark(1)	60	Chairperson of the Board of Directors
Cynthia Butitta(1)(3)	66	Director
Sandra Horning, M.D	71	Director
Gorjan Hrustanovic, Ph.D.(2)	32	Director
Frank McCormick, Ph.D., F.R.S., D.Sc. (Hon)(2)	70	Director
Andrew Rappaport(1)(3)	63	Director
Graham Walmsley, M.D., Ph.D.(2)(3)	34	Director
Key Consultant:		
Pamela M. Klein, M.D.	59	Chief Medical Officer

(1) Member of the compensation committee.

(2) Member of the nominating and corporate governance committee.

(3) Member of the audit committee.

Executive officers

Sean Bohen, M.D., Ph.D. has served as our Chief Executive Officer and as a member of our board of directors since September 2020. In September of 2020, Dr. Bohen joined Gyroscope Therapeutics, Ltd. as a non-executive director. In August 2019, Dr. Bohen joined AltruBio, Inc. (then AbGenomics, Inc.) as a non-executive director and continues in that role. From September 2015 to April 2019, Dr. Bohen served as the Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca PLC. From June 2003 to July 2015, he held a number of senior leadership roles at Genentech, Inc., including Senior Vice President, Early Development, Genentech Research and Early Development. Prior to Genentech, Dr. Bohen was a Clinical Instructor in Oncology at Stanford University School of Medicine from October 2002 to December 2011, a research associate at the Howard Hughes Medical Institute from July 2000 to June 2003 and a postdoctoral fellow at the National Cancer Institute from January through December 1995. Dr. Bohen received a B.S. in Bacteriology from the University of Wisconsin-Madison, and a Ph.D. in Biochemistry & Biophysics and M.D. from the University of California, San Francisco. We believe Dr. Bohen is qualified to serve on our board of directors due to his extensive experience in the biopharmaceutical industry as an executive officer, as well as the perspective and experience he brings as our President and Chief Executive Officer.

Cyrus L. Harmon, Ph.D. has served as our Chief Technology Officer since September 2020 and as a member of our board of directors since August 2006. Dr. Harmon is one of our co-founders, and he served as our President

and Chief Executive Officer from March 2007 to September 2020. From 2000 to 2002, Dr. Harmon served as the Vice President of Computational Genomics and General Manager at Affymetrix, Inc., later acquired by Thermo Fisher Scientific in 2016. From 1996 to 2000, Dr. Harmon founded and served as the Chief Executive Officer of Neomorphic, Inc., a computational biology company, before it was acquired by Affymetrix, Inc. Dr. Harmon received a B.A. and Ph.D. in molecular and cell biology from the University of California, Berkeley. We believe that Dr. Harmon is qualified to serve on our board of directors due to his extensive training as a scientist, significant knowledge and experience with respect to the biotechnology and pharmaceutical industries, and the perspective and experience he brings as one of our co-founders and executive officers.

Peter J. Kushner, Ph.D. has served as our Chief Scientific Officer since March 2007, served as a member of our board of directors from August 2006 to March 2020 and is one of our co-founders. He is also Professor Emeritus at the University of California, San Francisco, in the Department of Medicine, an association that began in 1986. From 1985 to 1986 he was a senior scientist at California Biotechnology. Dr. Kushner also co-founded Serra Pharmaceuticals, Inc. in 1996, which was acquired by Karo Bio (now Karo Pharma), and served on the board of directors of Karo Bio until 2004. Dr. Kusnher received a B.A. from Dartmouth College in mathematics honors and philosophy, and his Ph.D. in molecular biology from the Institute of Molecular Biology and Department of Biology at the University of Oregon in 1979. He was a post-doctoral fellow and Howard Hughes Research Associate at the University of California, San Francisco, in the Department of Biochemistry and Biophysics.

David C. Myles, Ph.D. has served as our Chief Development Officer since June 2020. Prior to that, he served as our Executive Vice President, Drug Discovery and Development beginning in April 2008. From 2006 to 2008, Dr. Myles co-founded and served as the Chief Operating Officer of Epiphany Biosciences, Inc. From January 2006 to November 2007, he served as the Executive Director of Chemistry at Kosan Biosciences, Inc. From 1998 to 2001, Dr. Myles served as the Associate Director of Medical Chemistry at Chiron Corporation, a biotechnology company that was later acquired by Novartis International AG. From 1991 to 1998, he was an Assistant Professor in the Department of Chemistry and Biochemistry at University of California, Los Angeles. Dr. Myles currently serves as the Finance Chair on Board of Directors of Point Blue. Dr. Myles received a B.A. in chemistry from Occidental College, and his Ph.D. in chemistry from Yale University. He was a National Institute of Health post-doctoral fellow at Harvard University.

Shane Kovacs has served as our Chief Operating and Financial Officer since June 2020. Prior to joining us, Mr. Kovacs served as Chief Business and Financial Officer at BlueRock Therapeutics LP from September 2018 to March 2020. Mr. Kovacs served as Managing Director, Head of Biotechnology Investment Banking at RBC Capital Markets from May 2017 to September 2018. From June 2013 to May 2017, Mr. Kovacs served in various positions at PTC Therapeutics, Inc., including Executive Vice President, Chief Financial Officer; Head of Corporate Development; and director of PTC Therapeutics International Limited, an indirect wholly owned subsidiary of PTC Therapeutics, Inc. From March 2004 to May 2013, Mr. Kovacs served in various positions at Credit Suisse, including Managing Director, Healthcare Investment Banking. Mr. Kovacs received a B.Eng. in chemical engineering and a B.S. in life sciences from Queen's University and an M.B.A. from the University of Western Ontario.

Kinney Horn has served as our Chief Business Officer since May 2020. From May 2019 to April 2020, Mr. Horn was an Entrepreneur in Residence at EcoR1 Capital, an investment advisory firm focused on biotechnology. From January 2003 to April 2019, Mr. Horn served as the Director of Business Development at Genentech, Inc. Prior to Genentech, Mr. Horn served in various investment banking and venture capital roles from 1998 to 2003. Mr. Horn received a B.A. in economics and international affairs from University of Mary Washington and an M.S. in biochemistry from Georgetown University.

John B. Moriarty, Jr., J.D. has served as our Executive Vice President, Chief Legal Officer and Corporate Secretary since September 2020. From March 2018 to July 2020, he served as Executive Vice President, General Counsel and Secretary at Portola Pharmaceuticals, Inc., which was acquired by Alexion Pharmaceuticals, Inc. in July 2020. From September 2014 to February 2018, Mr. Moriarty served as Executive Vice President and General Counsel of Alexion Pharmaceuticals, Inc., and from December 2012 to September 2014, he served as Senior Vice President and General Counsel of Alexion. Prior to joining Alexion in December 2012, he served as General Counsel and Chief Legal Officer at Elan Corporation plc, an Irish public limited company traded on the New York and Irish Stock

Exchanges, and also served as a member of Elan's Executive Management team from March 2010 to December 2012. Prior to assuming the role of General Counsel and Chief Legal Officer, Mr. Moriarty served as Senior Vice President of Law, Litigation and Commercial Operations at Elan from December 2008 to March 2010. From 2002 to 2008, Mr. Moriarty held various positions with Amgen Inc., including Executive Director and Associate General Counsel, Global Commercial Operations—Amgen Oncology and Senior Counsel, Complex Litigation, Products Liability and Government Investigations. From 1994 and 2002, Mr. Moriarty served in various capacities in private practice focused on healthcare and as a healthcare fraud prosecutor in the U.S. Attorney's Office and the Virginia Attorney General's Office. Mr. Moriarty received a B.A. from the University of Virginia and J.D. from the University of Georgia School of Law.

Non-employee directors

Andrew Rappaport has served as a member of our board of directors since January 2013. Mr. Rappaport has served as the Managing Partner at Skyline Public Works, LLC, his family office, since 2003, and as the Managing Partner and Chief Investment Officer of SPW Investments, his family investment vehicle since 2005. Between 1996 and 2014, Mr. Rappaport was a partner at August Capital, a leading technology venture capital firm. Prior to August Capital, he was the President of the Technology Research Group, a global strategy consulting firm he founded in 1984. We believe Mr. Rappaport is qualified to serve on our board of directors due to his investment experience in the technology industry and his deep knowledge of our company.

Cynthia Butitta has served as a member of our board of directors since August 2020. Ms. Butitta served as the Chief Operating Officer of Kite Pharma Inc., a biopharmaceutical company, from March 2014 to September 2017 and as its Executive Vice President and Chief Financial Officer from January 2014 to May 2016. From May 2011 to December 2012, she was Senior Vice President and Chief Financial Officer at NextWave Pharmaceuticals, Inc., a specialty pharmaceutical company. Prior to that, Ms. Butitta served as Chief Operating Officer of Telik, Inc., a biopharmaceutical company, from March 2001 to December 2010 and as its Chief Financial Officer from August 1998 to December 2010. Ms. Butitta also served as Principal Accounting Officer of Telik, Inc. until December 2010. She has served as a member of the board of directors of Autolus Therapeutics plc and UroGen Pharma Ltd., both publicly traded biopharmaceutical companies, since March 2018 and October 2017, respectively. Ms. Butitta received a B.S. with honors in business and accounting from Edgewood College in Madison, Wisconsin and an M.B.A. in finance from the University of Wisconsin, Madison. We believe Ms. Butitta is qualified to serve on our board of directors due to her extensive executive experience in the biopharmaceutical industry.

Ian Clark has served as a member of our board of directors since August 2020. From September 2017 to September 2020, Mr. Clark was an Operating Partner at Blackstone Life Sciences, formerly Clarus Ventures, LLC, a venture capital firm. Mr. Clark has served as a member of the boards of directors of publicly traded biopharmaceutical companies Takeda Pharmaceutical Company Limited since January 2019, AVROBIO, Inc. since January 2018, Corvus Pharmaceuticals, Inc. since January 2017, Guardant Health, Inc. since January 2017 and Agios Pharmaceuticals, Inc. since December 2016. Mr. Clark served as a member of the board of directors of publicly traded biopharmaceutical companies Forty Seven Inc. from May 2018 to April 2020, and Shire Pharmaceuticals, Inc. from February 2017 to January 2019. He also served as a member of the board of directors of Kite Pharma, Inc., then a publicly traded biopharmaceutical company, from January 2017 to October 2017. He served as Chief Executive Officer of Genentech, Inc. from January 2010 to December 2016. Prior to that, he was the Executive Vice President and Chief Marketing Officer of the Roche Group from April 2009 to December 2009. Prior to Roche Group, Mr. Clark held several senior management positions at Genentech from January 2003 to March 2009, including Head of Global Product Strategy, Chief Marketing Officer, Senior Vice President, General Manager of BioOncology and Executive Vice President, Commercial Operations. Prior to Genentech, Mr. Clark spent 23 years in the biopharmaceutical industry in senior roles at Novartis International AG, Ivax Pharmaceuticals, Inc. and Sanofi S.A. in the United Kingdom, France and Eastern Europe. He started his career at G.D. Searle, LLC, a subsidiary of Monsanto Corporation, holding positions in sales and marketing. Mr. Clark received a B.S. in biology from Southhampton University. We believe Mr. Clark is qualified to serve on our board of directors due to his extensive experience in the biopharmaceutical industry, both as an executive officer and as a director of multiple public and private companies.

Sandra J. Horning, M.D. has served as a member of our board of directors since November 2020. Dr. Horning served as the Chief Medical Officer and Global Head of Product Development of Roche, Inc., from January 2013 until her retirement in October 2019, and prior to that as Global Head of Oncology Product Development of Roche, Inc. from September 2009 to December 2013. From July 1980 until August 2009, Dr. Horning was a practicing oncologist, investigator and tenured professor at Stanford University School of Medicine, where she remains a professor of medicine emerita. From 2005 to 2006, Dr. Horning served as the President of the American Society of Clinical Oncology. From April 2015 to July 2018, Dr. Horning served as a member of the board of directors of Foundation Medicine, Inc., a previous publicly traded molecular information company. She has served as a member of the board of directors of Moderna, Inc., a publicly traded biotechnology company, since March 2020, and Gilead Sciences, Inc., a publicly traded biopharmaceutical company, since January 2020. Dr. Horning is also an advisor to and member of the board of EQRx, Inc., a biotechnology company. Dr. Horning received her M.D. from the University of Iowa School of Medicine and completed her internal medicine training at the University of Rochester and a fellowship in Oncology at Stanford University. We believe that Dr. Horning is qualified to serve on our board of directors due to her significant experience in the field of oncology and her product development leadership experience.

Gorjan Hrustanovic, Ph.D. has served as a member of our board of directors since July 2018. Dr. Hrustanovic has served as a Principal at BVF Partners L.P. since July 2018 and as an Analyst from September 2015 to July 2018. Dr. Hrustanovic also serves as a member of the boards of directors of Kymera Therapeutics Inc., a publicly traded biopharmaceutical company, a position he has held since March 2020, and a number of privately held companies, including Rain Therapeutics Inc. Dr. Hrustanovic received a B.S. in molecular biology and a B.S. in management science from the University of California, San Diego, and his Ph.D. in cancer biology & cell signaling from the University of California, San Francisco. We believe Dr. Hrustanovic is qualified to serve on our board of directors due to his experience in the life sciences industry as a venture capitalist and a director.

Frank McCormick, Ph.D., F.R.S., D.Sc. (Hon) has served as a member of our board of directors since December 2014. Dr. McCormick has served as the Chairman of Oncology at BridgeBio Pharma, Inc. since April 2019. He has held the position of Director the University of California, San Francisco Helen Diller Family Comprehensive Cancer Center, a multidisciplinary research and medical care organization and served as Associate Dean of the University of California, San Francisco School of Medicine from 1997 to 2014. Prior to joining the University of California, San Francisco faculty, Dr. McCormick pursued cancer-related work with several biotechnology firms, including Cetus Corporation as Director of Molecular Biology from 1981 to 1990 and Vice President of Research from 1990 to 1991, and Chiron Corporation as Vice President of Research from 1991 to 1992. In 1992, he founded Onyx Pharmaceuticals Inc. and served as its Chief Scientific Officer until 1996. He also served as a member of the board of directors of Aduro Biotech, Inc., a publicly traded biotechnology company, from 2010 to February 2019. Dr. McCormick received his B.Sc. in biochemistry from the University of Birmingham, and his Ph.D. in biochemistry from the University of Cambridge and held postdoctoral fellowships in the U.S. at the State University of New York at Stony Brook and in London at the Imperial Cancer Research Fund. Dr. McCormick is a Fellow of the Royal Society, an institution dedicated to science, since 1996, a member of the National Academy of Sciences since 2014 and has served as President, from 2012 to 2013, for the American Association for Cancer Research. Since 2013, Dr. McCormick has led the National Cancer Institute's Ras Initiative at the Frederick National Laboratories for Cancer Research overseeing the national effort to develop therapies against Ras-driven cancers. We believe Dr. McCormick is qualified to serve on our board of directors due to his scientific expertise and experience as a director of a publicly traded company.

Graham Walmsley, M.D., Ph.D. has served as a member of our board of directors since March 2020. Dr. Walmsley is a Founding Member and has served as a General Partner of Logos Global Management, LP, a biotechnology-focused hedge fund, since August 2019. From July 2016 to August 2019, he served as a Principal at Versant Ventures, a healthcare focused venture capital firm. Dr. Walmsley served as Head of Business Development at Pipeline Therapeutics Inc., a biotechnology company, from April 2018 to December 2018 and as Head of Business Development at Jecure Therapeutics, Inc., a biotechnology company, from June 2017 until its acquisition by Genentech, Inc., a subsidiary of Roche, in November 2018. He has served as a member of the board of directors of Akero Therapeutics and ALX Oncology Holdings Inc., both publicly traded biotechnology companies,

since June 2018 and February 2020, respectively. Dr. Walmsley received a B.A. in molecular and cell biology from the University of California, Berkeley and a Ph.D. and an M.D. in stem cell biology and regenerative medicine from Stanford University School of Medicine. We believe Dr. Walmsley is qualified to serve on our board of directors due to his extensive background in the biotechnology industry and experience as a director of a publicly traded company.

Key consultant

Pamela M. Klein, M.D. has served as our Chief Medical Officer since September 2020 and prior to that served as our acting Chief Medical Officer beginning in December 2018. Dr. Klein founded PMK BioResearch, of which she is a principal, in 2008. Through PMK BioResearch, Dr. Klein has offered strategic consulting in oncology drug development to corporate boards, management teams and the investment community, including consulting for and advising Syndax Pharmaceuticals, Inc. from 2008 to 2015. From 2009 to 2011, she served as Chief Medical Officer of Intellikine, Inc., a privately held pharmaceutical company that was acquired by Takeda Pharmaceuticals Company Limited. From 2001 to 2007, Dr. Klein worked at Genentech, Inc. and held roles of increasing responsibility including Vice President, Development. Prior to Genentech, she spent seven years at the National Cancer Institute, most recently as co-founder and Research Director of the NCI-Navy Breast Care Center. Dr. Klein has served on the boards of directors of I-Mab, a publicly traded biopharmaceutical company, Spring Bank Pharmaceuticals, Inc., a publicly traded biopharmaceutical company, and argenx SE, a publicly traded biotechnology company, since January 2020, July 2019, and April 2016, respectively, and also serves as a board member of Patrys Limited, a biotechnology company listed on the Australian Securities Exchange. She also serves as a member of various scientific advisory boards. Dr. Klein received a B.A. in biology from California State University, Northridge and an M.D. from Stritch School of Medicine, Loyola University Chicago.

Family relationships

Dr. Kushner is Dr. Harmon's uncle by marriage. There are no other family relationships among any of our executive officers or directors.

Composition of our board of directors

Our business and affairs are organized under the direction of our board of directors, which currently consists of nine members with no vacancies. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Certain members of our board of directors were elected under the provisions of our Amended and Restated Voting Agreement entered into in September 2020, or the Voting Agreement, which will terminate upon the closing of this offering. Under the terms of our Voting Agreement, the stockholders who are party to the Voting Agreement have agreed to vote their respective shares to elect: (i) one director designated by BVF Partners L.P., currently Gorjan Hrustanovic, Ph.D.; (ii) one director designated by Logos Global Management LP, currently Graham Walmsley, M.D., Ph.D.; (iii) one director designated by BVF Partners L.P., Logos Global Management LP and Janus Capital Management LLC, currently Cynthia Butitta; (iv) two directors designated by the holders of our common stock, one of whom shall be our then-current Chief Executive Officer, currently Sean Bohen, M.D., Ph.D., and one of whom shall be designated by the majority of then-outstanding shares of our common stock, currently Andrew Rappaport; and (v) the balance of the authorized number of directors, such individuals to be designated by our board of directors with the consent of at least one of the directors designated pursuant to (i), (ii) or (iii) and the consent of one of the directors designated pursuant to (iv), currently Frank McCormick, Ph.D., F.R.S., D.Sc. (Hon), Ian Clark and Cyrus L. Harmon, Ph.D. The Voting Agreement will terminate upon the closing of this offering, and upon the closing of the offering no stockholder will have any special rights regarding the election or designation of the members of our board of directors. Our current directors elected to our board of directors pursuant to the Voting Agreement will continue to serve as directors until their successors are duly elected and qualified by holders of our common stock.

Our board of directors may establish the authorized number of directors from time to time by resolution. In accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be Mr. Clark, Dr. Horning and Dr. Hrustanovic, and their terms will expire at the annual meeting of stockholders to be held in 2021;
- the Class II directors will be Ms. Butitta, Dr. Harmon and Dr. Walmsley, and their terms will expire at the annual meeting of stockholders to be held in 2022; and
- the Class III directors will be Dr. Bohen, Dr. McCormick and Mr. Rappaport, and their terms will expire at the annual meeting of stockholders to be held in 2023.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director independence

Under the listing requirements and rules of The Nasdaq Stock Market LLC, or the Nasdaq Listing Rules, independent directors must comprise a majority of our board of directors as a listed company within one year of the listing date.

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning her or his background, employment and affiliations, including family relationships, our board of directors has determined that Messrs. Clark and Rappaport, Ms. Butitta, and Drs. Horning, Hrustanovic, McCormick and Walmsley, representing seven of the nine directors, do not have relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is “independent” as that term is defined under the Nasdaq Listing Rules. Our board of directors has determined that Drs. Bohen and Harmon, by virtue of their positions as our President and Chief Executive Officer and Chief Technology Officer, respectively, are not independent under applicable rules and regulations of the U.S. Securities and Exchange Commission, or the SEC, and the Nasdaq Listing Rules. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director and the transactions described in the section titled “Certain Relationships and Related Person Transactions.”

Committees of our board of directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee intends to adopt a written charter that satisfies the application rules and regulation of the SEC and the Nasdaq Listing Rules, which we will post to our website at www.olema.com upon the closing of this offering. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit committee

Our audit committee currently consists of Ms. Butitta, Mr. Rappaport, and Dr. Walmsley, each of whom our board of directors has determined satisfies the independence requirements under Nasdaq Listing Rules and

Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The chair of our audit committee is Ms. Butitta, who our board of directors has determined is an "audit committee financial expert" within the meaning of SEC regulations. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our corporate accounting and financial reporting processes, systems of internal control and financial-statement audits, and to oversee our independent registered accounting firm. Specific responsibilities of our audit committee include:

- helping our board of directors oversee our corporate accounting and financial reporting processes;
- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving, or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

Compensation committee

Our compensation committee currently consists of Messrs. Clark and Rappaport and Ms. Butitta. The chair of our compensation committee is Mr. Clark. Our board of directors has determined that each of is independent under the Nasdaq Listing Rules and as a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors in overseeing our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers, directors and other senior management, as appropriate. Specific responsibilities of our compensation committee include:

- reviewing and approving the compensation of our chief executive officer, other executive officers and senior management;
- reviewing and recommending to our board of directors the compensation paid to our directors;
- reviewing and approving the compensation arrangements with our executive officers and other senior management;
- administering our equity incentive plans and other benefit programs;
- reviewing, adopting, amending and terminating, incentive compensation and equity plans, severance agreements, profit sharing plans, bonus plans, change-of-control protections and any other compensatory arrangements for our executive officers and other senior management;
- reviewing, evaluating and recommending to our board of directors succession plans for our executive officers; and

- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation philosophy.

Nominating and corporate governance committee

Our nominating and corporate governance committee consists of Drs. Hrustanovic, McCormick and Walmsley. The chair of our nominating and corporate governance committee is Dr. Hrustanovic. Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the Nasdaq Listing Rules, a non-employee director, and free from any relationship that would interfere with the exercise of his or her independent judgment.

Specific responsibilities of our nominating and corporate governance committee include:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on our board of directors;
- considering and making recommendations to our board of directors regarding the composition and chairmanship of the committees of our board of directors;
- instituting plans or programs for the continuing education of our board of directors and orientation of new directors;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing periodic evaluations of the board of directors' performance, including committees of the board of directors and management.

Code of business conduct and ethics

We have adopted a written Code of Business Conduct and Ethics that applies to all our employees, officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our Code of Business Conduct and Ethics is posted on our website at www.olema.com. We intend to disclose on our website any future amendments of our Code of Business Conduct and Ethics or waivers that exempt any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors from provisions in the Code of Business Conduct and Ethics. Information contained on, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference.

Compensation committee interlocks and insider participation

None of the members of the compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last calendar year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Non-employee director compensation

During the year ended December 31, 2019, each of the following individuals served on our board of directors as non-employee directors: Marina Bozilenko, Lawrence Fritz, Gorjan Hrustanovic, Ph.D., Andrei Manoliu, Ph.D., Frank McCormick, Ph.D., F.R.S., D.Sc. (Hon), Andrew Rappaport and Peter Schwartz. Our non-employee directors did not earn any compensation in the year ended December 31, 2019. As of December 31, 2019, none of our non-employee directors other than Mr. Fritz, who held an option to purchase 3,586 shares of our common stock, and Dr. McCormick, who held an option to purchase 17,934 shares of our common stock, held any unvested equity awards. Drs. Harmon and Kushner each also served on our board of directors during the year ended December 31,

2019, but neither received any additional compensation for their service as a director. See the section titled “Executive Compensation” for more information regarding the compensation earned by Drs. Harmon and Kushner.

We have reimbursed and will continue to reimburse all of our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

Our board of directors adopted a non-employee director compensation policy in October 2020 that became effective in connection with this offering and will be applicable to all of our non-employee directors. This compensation policy provides that each such non-employee director will receive the following compensation for service on our board of directors:

- an annual cash retainer of $40,000;
- an additional cash retainer of $30,000 for the chairperson of our board of directors;
- an additional annual cash retainer of $8,000, $6,000 and $5,000 for service as a member of the audit committee, compensation committee and the nominating and corporate governance committee, respectively;
- an additional annual cash retainer of $8,000, $6,000 and $5,000 for service as chair of the audit committee, compensation committee and the nominating and corporate governance committee, respectively;
- an initial option grant to purchase 21,520 shares of our common stock on the date of each such non-employee director’s appointment to our board of directors, plus an additional grant representing the annual option grant such non-employee director would have received had he or she been elected to our board of directors at our prior annual meeting of stockholders, pro-rated for partial year of service; and
- an annual option grant to purchase 21,520 shares of our common stock on the date of each of our annual stockholder meetings.

Each of the option grants described above will be granted under our 2020 Plan, the terms of which are described in more detail below under the section titled “Executive Compensation—Equity Benefit Plans—2020 Equity Incentive Plan.” Each such option grant will vest and become exercisable subject to the director’s continuous service to us through the earlier of the first anniversary of the date of grant or the next annual stockholder meeting. The term of each option will be 10 years, subject to earlier termination as provided in the 2020 Plan.

Director IPO grants

Upon the effectiveness of our 2020 Plan, our board of directors granted options to purchase shares of our common stock, with an exercise price per share equal to the initial public offering price per share, to each of our non-employee directors in the following amounts:

- 21,520 shares to each of Mr. Clark, Ms. Butitta, Dr. McCormick and Mr. Rappaport;
- 64,560 shares to each of Drs. Hrustanovic and Walmsley; and
- 86,083 shares to Dr. Horning.

Executive compensation

Our named executive officers for the year ended December 31, 2019 were:

- Cyrus L. Harmon, Ph.D., our Chief Technology Officer and former President and Chief Executive Officer;
- Peter J. Kushner, Ph.D., our Chief Scientific Officer; and
- David C. Myles, Ph.D., our Chief Development Officer.

Summary compensation table

The following table presents all of the compensation awarded to or earned by or paid to our named executive officers during the fiscal year ended December 31, 2019.

Name and principal position	Fiscal year	Salary ($)	Total ($)
Cyrus L. Harmon, Ph.D. *Chief Technology Officer and Former President and Chief Executive Officer*[(1)]	2019	300,000	300,000
Peter J. Kushner, Ph.D. *Chief Scientific Officer*	2019	200,000	200,000
David C. Myles, Ph.D. *Chief Development Officer*	2019	200,000	200,000

(1) Dr. Harmon served as our Chief Executive Officer from March 2007 to September 2020, when he transitioned to the role of Chief Technology Officer. Dr. Bohen was appointed as our Chief Executive Officer in September 2020.

Narrative to the summary compensation table

Our board of directors reviews compensation annually for all employees, including our named executive officers. In making compensation determinations, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders and a long-term commitment to our company.

Our board of directors has historically determined our executive officers' compensation and has typically reviewed and discussed management's proposed compensation with our chief executive officer for all executives other than our chief executive officer. Based on those discussions and its discretion, our board of directors then approved the compensation of each executive officer. Upon the closing of this offering, the compensation committee will determine our executive officers' compensation and follow this process, but generally the compensation committee itself, rather than our board of directors, will approve the compensation of each executive officer.

Annual base salary

Base salaries for our executive officers are initially established through arm's-length negotiations at the time of the executive officer's hiring, taking into account such executive officer's qualifications, experience, the scope of his or her responsibilities and competitive market compensation paid by other companies for similar positions within the industry and geography. Base salaries are reviewed periodically, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. In making decisions regarding salary increases, we may also draw upon the experience of members of our board of directors with executives at other companies. The 2019 base salaries for our named executive officers are reflected in the table above.

Outstanding equity awards as of December 31, 2019

There were no outstanding equity incentive plan awards held by our named executive officers as of December 31, 2019.

We may in the future, on an annual basis or otherwise, grant additional equity awards to our executive officers pursuant to our 2020 Plan, the terms of which are described below under the section titled "—Equity Benefit Plans—2020 Equity Incentive Plan."

Emerging growth company status

We are an "emerging growth company," as defined in the JOBS Act. As an emerging growth company we will be exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our chief executive officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Pension benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during the fiscal year ended December 31, 2019.

Nonqualified deferred compensation

Our named executive officers did not participate in, or earn any benefits under, a non-qualified deferred compensation plan sponsored by us during the fiscal year ended December 31, 2019.

IPO Grants

At the time of effectiveness of the 2020 Plan, our board of directors granted options to purchase shares of our common stock to our named executive officers, with an exercise price equal to the initial public offering price per share. On such date, Drs. Harmon, Kushner and Myles were granted 179,340, 179,340 and 179,340 options to purchase shares of our common stock, respectively.

Employment, severance and change in control agreements

Offer letters

Below are descriptions of our offer letters and employment agreements with our named executive officers. For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in control under the arrangements with our named executive officers, see the section titled "—Potential Payments and Benefits Upon Termination or Change in Control" below.

Dr. Harmon. In June 2020, we and Dr. Harmon entered into an offer letter governing the terms of his employment. Pursuant to the offer letter, Dr. Harmon was entitled to an initial annual base salary, effective January 1, 2020, of $450,000, was eligible to receive an annual performance bonus with a target achievement of 45% of his base salary, as determined by our board of directors, and was granted a restricted stock award of 143,472 shares of our common stock (in addition to shares of our stock that Dr. Harmon held at the time we entered into his offer letter). In September 2020, in connection with his transition to the role of Chief Technology Officer, Dr. Harmon's annual base salary increased to $500,000, and he was granted an option to purchase 227,859 shares of our common stock.

In November 2020, we and Dr. Harmon entered into an amended and restated employment agreement that governs the current terms of his employment. Pursuant to the amended and restated employment agreement his

annual base salary will remain $500,000, and his annual performance bonus target achievement is equal to 40% of his base salary. Dr. Harmon remains eligible for future equity awards as determined by our board of directors.

Dr. Harmon is also entitled to certain severance benefits, the terms of which are described below under the section titled "—Potential Payments and Benefits Upon Termination or Change of Control." Dr. Harmons's employment is at will.

Dr. Kushner. In June 2020, we and Dr. Kushner entered into an offer letter governing the terms of his employment. Pursuant to the offer letter, Dr. Kushner was entitled to an initial annual base salary, effective January 1, 2020, of $350,000, was eligible to receive an annual performance bonus with a target achievement of 30% of his base salary, as determined by our board of directors, and was granted a restricted stock award of 143,472 shares of our common stock (in addition to shares of our stock that Dr. Kushner held at the time we entered into his offer letter).

In November 2020, we and Dr. Kushner entered into an amended and restated employment agreement that governs the current terms of his employment. Pursuant to the amended and restated employment agreement his annual base salary will remain $350,000, and his annual performance bonus target achievement remains equal to 30% of his base salary. Dr. Kushner remains eligible for future equity awards as determined by our board of directors.

Dr. Kushner is also entitled to certain severance benefits, the terms of which are described below under the section titled "—Potential Payments and Benefits Upon Termination or Change of Control." Dr. Kushner's employment is at will.

Dr. Myles. In June 2020, we and Dr. Myles entered into an offer letter governing the terms of his employment with us. Pursuant to the offer letter, Dr. Myles was entitled to an initial annual base salary, effective January 1, 2020, of $340,000, was eligible to receive an annual performance bonus with a target achievement of 30% of his base salary, as determined by our board of directors, and was granted a restricted stock award of 143,472 shares of our common stock (in addition to shares of our stock that Dr. Myles held at the time we entered into his offer letter).

In November 2020, we and Dr. Myles entered into an amended and restated employment agreement that governs the current terms of his employment. Pursuant to the amended and restated employment agreement his annual base salary will remain $340,000, and his annual performance bonus target achievement remains equal to 30% of his base salary. Dr. Myles remains eligible for future equity awards as determined by our board of directors.

Dr. Myles is also entitled to certain severance benefits, the terms of which are described below under the section titled "—Potential Payments and Benefits Upon Termination or Change of Control." Dr. Myles' employment is at will.

Potential payments and benefits upon termination or change of control

Pursuant to our named executive officers' amended and restated employment agreements, if (a) the officer's employment is terminated without cause (as defined below) or (b) the officer resigns for good reason (as defined below), then in addition to any amounts accrued and payable under the terms of our benefit plans through the date of termination, the officer will be entitled to receive severance as described below. The level of severance benefits will depend on whether or not the termination without cause or resignation for good reason occurs within a "change in control period" that begins three months before the effective date of a change in control (as defined below) and extends through the period ending 18 months following the effective date of a change in control.

If the officer's employment is terminated without cause or resignation for good reason outside of the change in control period, the officer will be entitled to receive severance in the form of 12 months of his then-current base

salary, such amount to be paid in equal installments over a twelve-month period after the date of termination, subject to applicable taxes and withholding, as well as up to 12 months of COBRA coverage. The officer will remain eligible for an annual bonus amount for the year of the separation of service to be determined by our board of directors based on corporate performance during the year and prorated based on months of service, subject to applicable taxes and withholding. In addition, 50% of his then-unvested time-based equity grants shall accelerate and become fully vested as of the termination date. Further, if the termination without cause or resignation for good reason occurs within the twelve-month period that immediately follows the closing of this offering, 100% of his then-unvested time-based equity grants made in connection with the commencement of his employment shall accelerate and become fully vested as of the termination date.

If the officer's employment is terminated without cause or resignation for good reason within the change in control period, the officer will be entitled to receive severance in the form of 12 months of his then-current base salary plus his target bonus for the year of termination to be paid in a lump sum, subject to applicable taxes and withholding, as well as up to 12 months of COBRA coverage. The officer will also remain eligible for an annual bonus amount for the year of the separation of service to be determined by our board of directors based on corporate performance during the year and prorated based on months of service. In addition, all his then-unvested time-based equity grants shall accelerate and become fully vested as of the termination date.

These severance benefits are conditioned upon the officer continuing to comply with his obligations under his proprietary information agreement and his delivery of a general release of claims in favor of the company that becomes effective and irrevocable within 60 days of the date of termination. In the event of any payments to our named executive officers being characterized as parachute payments under Section 280G of the Internal Revenue Code of 1986, as amended, or the Code, the officer will receive either a reduced payment amount or the full payment about, depending on which results in a more favorable economic benefit.

For the purposes of our named executive officers' severance benefits, the following definitions apply:

- "cause" means any of the following: (i) theft, breach of fiduciary duty, or intentional falsification of Olema documents or records; (ii) material failure to abide by any Olema policy after written notice from us regarding failure to abide by such policy; (iii) intentional and unauthorized use, misappropriation, destruction or diversion of any of our material tangible or intangible asset or corporate opportunity (including, without limitation, improper use or disclosure of our confidential or proprietary information); (iv) any intentional act that has a material detrimental effect on our reputation or business; (v) repeated failure or inability to perform any reasonable assigned duties after written notice from us of, and a reasonable opportunity to cure, such failure or inability; (vi) any material breach of any contractual or legal obligation to us and the failure to cure within ten days after delivery of written notice thereof (to the extent such breach or violation is curable); or (vii) conviction (including any plea of guilty or nolo contendere) of any felony.
- "change in control" means (i) a sale of all or substantially all of our assets other than to an excluded entity (as defined below); (ii) a merger, consolidation or other capital reorganization or business combination transaction of Olema with or into another corporation, limited liability company or other entity other than an excluded entity; or (iii) the consummation of a transaction, or series of related transactions, in which 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 all of our then outstanding voting securities. An "excluded entity" means a corporation or other entity of which the holders of voting capital stock of our outstanding immediately prior to such transaction are the direct or indirect holders of voting securities representing a majority of the votes entitled to be cast by all of such corporation's or other entity's voting securities outstanding immediately after such transaction.
- "good reason" means (i) a material diminution in total target cash compensation (base and bonus) of more than 10% except for across-the-board salary reductions similarly affecting all or substantially all of our senior executives; (ii) a change in the geographic location of the named executive officer's primary place of work that results in an increase in one-way commute by more than 25 miles (provided, however, that subclause (ii) shall only be applicable after the we resume normal in-person office operations in connection with the

COVID-19 pandemic); (iii) a material reduction in job duties or responsibilities reporting directly to the Chief Executive Officer; or (iv) a material breach of the agreement by us; provided, however, that the named executive officer shall not be deemed to have good reason if we survive as a separate legal entity following a change in control and the named executive officer holds materially the same position in such legal entity as before the change in control. A resignation will only be for good reason if the named executive officer delivers written notice of such condition to us within 30 days after the initial occurrence of such condition, we have failed to cure such condition within 30 days after the delivery of such notice, and the named executive officer in fact resigns within 45 days after delivering the initial notice.

Other compensation and benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental and vision plans, in each case on the same basis as all of our other employees. We pay the premiums for the medical, disability, accidental death and dismemberment insurance for all of our employees, including our named executive officers. Other than a parking space for our Dr. Harmon, we generally do not provide perquisites or personal benefits to our named executive officers.

Equity benefit plans

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant options and other equity-based awards helps us to attract, retain and motivate employees, consultants and directors, and encourages them to devote their best efforts to our business and financial success. The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus forms a part.

2020 equity incentive plan

Our board of directors adopted, and our stockholders approved, our 2020 Equity Incentive Plan, or 2020 Plan. Our 2020 Plan became effective on the date of the underwriting agreement related to this offering. Our 2020 Plan came into existence upon its adoption by our board of directors. Since our 2020 Plan became effective, no further grants will be made under our 2014 Stock Plan, or the 2014 Plan.

Awards. Our 2020 Plan provides for the grant of incentive stock options, or ISOs, within the meaning of Section 422 of the Code, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to our employees, directors and consultants and any of our affiliates' employees and consultants.

Authorized Shares. Initially, the maximum number of shares of our common stock that may be issued under our 2020 Plan after it became effective will not exceed 6,494,510 shares of our common stock, which is the sum of (i) 2,152,080 new shares, plus (ii) an additional number of shares not to exceed 4,342,430 shares, consisting of any shares of our common stock subject to outstanding stock options or other stock awards granted under our 2014 Plan that, on or after our 2020 Plan became effective, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. In addition, the number of shares of our common stock reserved for issuance under our 2020 Plan will automatically increase on January 1 of each year for a period of ten years, beginning on January 1, 2021 and continuing through January 1, 2030, in an amount equal to the lesser of (1) 5% of the total number of shares of our common stock outstanding on December 31 of the immediately preceding year, or (2) a lesser number of shares determined by our board of directors no later than December 31 of the immediately preceding year. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2020 Plan is 19,483,530 shares.

Shares subject to stock awards granted under our 2020 Plan that expire or terminate without being exercised in full or that are paid out in cash rather than in shares will not reduce the number of shares available for issuance under our 2020 Plan. Shares withheld under a stock award to satisfy the exercise, strike or purchase price of a stock award or to satisfy a tax withholding obligation will not reduce the number of shares available for issuance under our 2020 Plan. If any shares of our common stock issued pursuant to a stock award are forfeited back to or repurchased or reacquired by us (i) because of a failure to meet a contingency or condition required for the vesting of such shares; (ii) to satisfy the exercise, strike or purchase price of a stock award; or (iii) to satisfy a tax withholding obligation in connection with a stock award, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under our 2020 Plan.

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors, administers our 2020 Plan. Our board of directors may delegate to one or more of our officers the authority to (i) designate employees (other than officers) to receive specified stock awards; and (ii) determine the number of shares subject to such stock awards. Under our 2020 Plan, our board of directors will have the authority to determine stock award recipients, the types of stock awards to be granted, grant dates, the number of shares subject to each stock award, the fair market value of our common stock, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

Under our 2020 Plan, our board of directors also generally has the authority to effect, with the consent of any materially adversely affected participant, (i) the reduction of the exercise, purchase, or strike price of any outstanding option or stock appreciation right; (ii) the cancellation of any outstanding option or stock appreciation right and the grant in substitution therefore of other awards, cash, or other consideration; or (iii) any other action that is treated as a repricing under generally accepted accounting principles.

Stock Options. ISOs and NSOs are granted under stock option agreements adopted by the administrator. The administrator will determine the exercise price for stock options, within the terms and conditions of our 2020 Plan, except the exercise price of a stock option generally will not be less than 100% of the fair market value of our common stock on the date of grant. Options granted under our 2020 Plan vest at the rate specified in the stock option agreement as will be determined by the administrator.

The administrator will determine the term of stock options granted under our 2020 Plan, up to a maximum of 10 years. Unless the terms of an optionholder's stock option agreement, or other written agreement between us and the recipient, provide otherwise, if an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death, or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the administrator and may include (i) cash, check, bank draft or money order; (ii) a broker-assisted cashless exercise; (iii) the tender of shares of our common stock previously owned by the optionholder; (iv) a net exercise of the option if it is an NSO; or (v) other legal consideration approved by the administrator.

Unless the administrator provides otherwise, options or stock appreciation rights generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the administrator or a duly authorized officer, an option may be transferred pursuant to a domestic relations order, official marital settlement agreement, or other divorce or separation instrument.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of

our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant; and (ii) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards. Restricted stock unit awards are granted under restricted stock unit award agreements adopted by the administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, or other written agreement between us and the recipient, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements adopted by the administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past or future services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The administrator will determine the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights are granted under stock appreciation right agreements adopted by the administrator. The administrator will determine the purchase price or strike price for a stock appreciation right, which generally will not be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under our 2020 Plan will vest at the rate specified in the stock appreciation right agreement as will be determined by the administrator. Stock appreciation rights may be settled in cash or shares of our common stock or in any other form of payment as determined by our board of directors and specified in the stock appreciation right agreement.

The administrator will determine the term of stock appreciation rights granted under our 2020 Plan, up to a maximum of 10 years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability, or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate upon the termination date. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. Our 2020 Plan permits the grant of performance awards that may be settled in stock, cash or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, our common stock.

The performance goals may be based on any measure of performance selected by our board of directors. The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates, or business segments, and may be either absolute or relative to the performance of one or

more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by our board of directors at the time the performance award is granted, our board will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (i) to exclude restructuring or other nonrecurring charges; (ii) to exclude exchange rate effects; (iii) to exclude the effects of changes to generally accepted accounting principles; (iv) to exclude the effects of any statutory adjustments to corporate tax rates; (v) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (vi) to exclude the dilutive effects of acquisitions or joint ventures; (vii) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (viii) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (ix) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (x) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (xi) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

Other Stock Awards. The administrator is permitted to grant other awards based in whole or in part by reference to our common stock. The administrator will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid to any non-employee director with respect to any calendar year, including awards granted and cash fees paid by us to such non-employee director, will not exceed $750,000 in total value, except such amount will increase to $1,500,000 for the first year for newly appointed or elected non-employee directors.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under our 2020 Plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued on the exercise of ISOs, and (iv) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. In the event of a corporate transaction (as defined below), unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the administrator at the time of grant, any stock awards outstanding under our 2020 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full (or, in the case of performance awards with multiple vesting levels depending on the level of performance, vesting will accelerate at 100% of the target level) to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction); and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

In the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such

stock award but instead will receive a payment equal in value to the excess (if any) of (i) the value of the property the participant would have received upon the exercise of the stock award, over (ii) any per share exercise price payable by such holder, if applicable. In addition, any escrow, holdback, earn out or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of our common stock.

Under our 2020 Plan, a "corporate transaction" is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets; (ii) a sale or other disposition of at least 50% of our outstanding securities; (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation; or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change in Control. Stock awards granted under our 2020 Plan may be subject to acceleration of vesting and exercisability upon or after a change in control (as defined below) as may be provided in the applicable stock award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur.

Under our 2020 Plan, a "change in control" is generally (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction; (iii) stockholder approval of a complete dissolution or liquidation; (iv) a sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction; or (v) when a majority of our board of directors becomes comprised of individuals who were not serving on our board of directors on the date of the underwriting agreement related to this offering, or the incumbent board, or whose nomination, appointment, or election was not approved by a majority of the incumbent board still in office.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend, or terminate our 2020 Plan at any time, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopts our 2020 Plan. No stock awards may be granted under our 2020 Plan while it is suspended or after it is terminated.

2014 stock plan

Our board of directors adopted the 2014 Plan in December 2014, and our stockholders adopted the 2014 Plan in the same month. The 2014 Plan provides for the grant of ISOs, NSOs, restricted stock purchase rights and restricted stock bonuses, to our employees, directors and consultants. ISOs may be granted only to our employees or employees of our affiliates.

The 2014 Plan was terminated on the date the 2020 Plan became effective. However, any outstanding awards granted under the 2014 Plan will remain outstanding, subject to the terms of our 2014 Plan and award agreements, until such outstanding options are exercised or until any awards terminate or expire by their terms.

Authorized Shares. Upon the effective date of the 2020 Plan, we will no longer grant awards under our 2014 Plan. As of September 30, 2020, options to purchase 2,505,811 shares of our common stock were outstanding, and 1,175,022 shares of our common stock remained available for future issuance under our 2014 Plan. The options outstanding as of September 30, 2020 had a weighted-average exercise price of $4.14 per share. Subject to capitalization adjustment, the maximum aggregate number of shares of common stock that may be issued under the 2014 Plan is 4,842,180 shares, and the maximum number of shares issuable pursuant to ISOs is 12,374,461 shares.

Plan Administration. Our board or a duly authorized committee of our board administers our 2014 Plan and the awards granted under it. The administrator has the power to modify outstanding awards under our 2014 Plan. In addition to other powers set forth in the 2014 Plan, our board has the full and final power and authority, in its discretion to: (1) determine the persons to whom awards shall be granted; (2) the type of award granted; (3) the fair market value of shares; (4) the terms, conditions and restrictions applicable to each award and any shares acquired pursuant thereto; (5) approve one or more form of award agreement; (6) amend, modify, extend, cancel or renew any award to waive any restrictions or conditions applicable to any award or shares; (7) accelerate, continue, extend or defer the exercisability or vesting of any award or shares acquired pursuant thereto; (8) prescribe, amend or rescind rules, guidelines and policies relating to the plan and to adopt sub-plans or supplements to or alternative versions of the plan; and (9) to correct any defect, supply any omission or reconcile any inconsistency in the plan of any award agreement and to make all other determinations and take such other actions with respect to the plan or any award agreement and make all determinations and take other actions with respect to the plan or any award agreement.

Corporate Transactions. Our 2014 Plan provides that in the event of certain specified significant corporate transactions, as defined under our 2014 Plan, our board may (1) accelerate vesting of outstanding awards (2) arrange for the assumption, continuation or substitution of an award by an acquiror; (3) cancel and exchange awards for a payment in cash, stock, or other property equal to the fair market value of the shares being canceled minus any exercise or purchase price.

Transferability. The 2014 Plan imposes limitations on the transferability of ISOs and NSOs. During a participant's lifetime an option may only be exercised by a participant. The Board may permit the transfer of options as set forth in an award agreement as permitted by Rule 701 of the Securities Act of 1933, as amended, or the Securities Act, the General Instructions to the Form S-8 Registration Statement or for ISOs only, Section 421 of the Code.

Plan Amendment or Termination. Our board has the authority to amend, suspend or terminate our 2014 Plan at any time, subject to stockholder approval if required by law or stock exchange rules. Additionally, no amendment, suspension or termination may have any materially adverse effect on any then outstanding award without the consent of the participant. As described above, our 2014 Plan was terminated upon the effective date of the 2020 Plan and no future awards will be granted under the 2014 Plan following such termination.

2020 employee stock purchase plan

Our board of directors adopted, and our stockholders approved, our 2020 Employee Stock Purchase Plan, or ESPP. Our ESPP became effective immediately prior to and contingent upon the date of the underwriting agreement related to this offering. The purpose of our ESPP is to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. Our ESPP includes two components. One component is designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. The other component permits the grant of purchase rights that do not qualify for such favorable tax treatment in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the U.S. while complying with applicable foreign laws.

Share Reserve. Following this offering, our ESPP authorizes the issuance of 430,416 shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each year for a period of ten years, beginning on January 1, 2021 and continuing through January 1, 2030, by the lesser of (i) 1% of the total number of shares of our common stock outstanding on December 31 of the immediately preceding year; and (ii) 860,832 shares, except before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii).

Administration. Our board of directors administers our ESPP and may delegate its authority to administer our ESPP to our compensation committee. Our ESPP will be implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during

such offerings. Under our ESPP, our board of directors is permitted to specify offerings with durations of not more than 27 months and to specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. Our ESPP provides that an offering may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, are eligible to participate in our ESPP and to contribute, normally through payroll deductions, up to 15% of their earnings (as defined in our ESPP) for the purchase of our common stock under our ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in our ESPP at a price per share equal to the lesser of (i) 85% of the fair market value of a share of our common stock on the first day of an offering; or (ii) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in our ESPP, as determined by our board of directors: (i) being customarily employed for more than 20 hours per week; (ii) being customarily employed for more than five months per calendar year; or (iii) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee will be permitted to purchase shares under our ESPP at a rate in excess of $25,000 worth of our common stock (based on the fair market value per share of our common stock at the beginning of an offering) for each calendar year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under our ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

Changes to Capital Structure. Our ESPP provides that in the event there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, our board of directors will make appropriate adjustments to: (i) the class(es) and maximum number of shares reserved under our ESPP; (ii) the class(es) and maximum number of shares by which the share reserve may increase automatically each year; (iii) the class(es) and number of shares subject to, and purchase price applicable to, outstanding offerings and purchase rights; and (iv) the class(es) and number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. Our ESPP provides that in the event of a corporate transaction (as defined below), any then-outstanding rights to purchase our stock under our ESPP may be assumed, continued, or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within 10 business days before such corporate transaction, and such purchase rights will terminate immediately after such purchase.

Under our ESPP, a "corporate transaction" is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets; (ii) a sale or other disposition of at least 50% of our outstanding securities; (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation; or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Amendment or Termination. Our board of directors has the authority to amend or terminate our ESPP, except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Limitations on liability and indemnification

Our amended and restated certificate of incorporation, which will become effective immediately after the closing of this offering, will contain provisions that limit the liability of our current and former directors for monetary

damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation will authorize us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws will provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws will also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding.

We believe that these amended and restated certificate of incorporation and amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers, or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Rule 10b5-1 plans

Our directors, officers and key consultant may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades under parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they do not possess of material nonpublic information, subject to compliance with the terms of our insider trading policy. During the first 180 days from this offering, the sale of any shares under such plan would be subject to the lock-up agreement that the director or officer has entered into with the underwriters.

Certain relationships and related person transactions

The following includes a summary of transactions since January 1, 2017 and any currently proposed transactions to which we have been or are to be a party in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under the section titled “Executive Compensation.” We also describe below certain other transactions with our directors, executive officers and stockholders.

Series C convertible preferred stock financing

In September 2020, we completed the closing of an aggregate of 7,904,135 shares of our Series C convertible preferred stock at a purchase price of $11.063 per share.

The following table summarizes purchases of shares of our Series C convertible preferred stock by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

Participants[1]	Shares of Series C convertible preferred stock purchased for cash (#)	Aggregate purchase price
Entities affiliated with BVF Partners L.P.[2]	1,355,957	$ 14,999,998
Entities affiliated with Cormorant Asset Management, LP[3]	723,177	$ 7,999,998
Entities managed by Janus Capital Management LLC[4]	741,256	$ 8,200,000
Entities affiliated with RA Capital Management, L.P.[5]	451,985	$ 4,999,997
Logos Opportunities Fund II, L.P.	1,183,114	$ 13,087,946
Wellington Biomedical Innovation Master Investors (Cayman) I L.P.	451,986	$ 4,999,997

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the section titled “Principal Stockholders.”

(2) Consists of (i) 760,155 shares of Series C convertible preferred stock purchased by Biotechnology Value Fund L.P., or BVF, (ii) 522,403 shares of Series C convertible preferred stock purchased by Biotechnology Value Fund II, L.P., or BVF2, and (iii) 73,399 shares of Series C convertible preferred stock purchased by Biotechnology Value Trading Fund OS L.P., or Trading Fund OS. Dr. Hrustanovic, a member of our board of directors, is a Principal of BVF Partners L.P.

(3) Consists of (i) 587,871 shares of Series C convertible preferred stock purchased by Cormorant Private Healthcare Fund III, LP, (ii) 126,122 shares of Series C convertible preferred stock purchased by Cormorant Global Healthcare Master Fund, LP, or Cormorant Master Fund, and (iii) 9,184 shares of Series C convertible preferred stock purchased by CRMA SPV, L.P, or CRMA.

(4) Janus Capital Management LLC, or Janus Capital, is an independent investment advisor registered under the Investment Advisers Act of 1940. Shares held by entities for whom Janus Capital is the investment advisor and who are holding our securities are aggregated for purposes of reporting share ownership information, including (i) 379,331 shares of Series C convertible preferred stock purchased by Janus Henderson Global Life Sciences Fund, or Janus Global Fund, (ii) 354,859 shares of Series C convertible preferred stock purchased by Janus Henderson Capital Funds PLC on behalf of its series Janus Henderson Global Life Sciences Fund, or Janus Capital Funds, and (iii) 7,066 shares of Series C convertible preferred stock purchased by Janus Henderson Horizon Fund—Biotechnology Fund.

(5) Consists of (i) 307,739 shares of Series C convertible preferred stock purchased by RA Capital Healthcare Fund, L.P., (ii) 112,996 shares of Series C convertible preferred stock purchased by RA Capital Nexus Fund, L.P., and (iii) 31,250 shares of Series C convertible preferred stock purchased by Blackwell Partners LLC—Series A.

2020 convertible notes and Series B convertible preferred stock financing

In January 2020, we issued convertible promissory notes in the aggregate principal amount of $3.0 million to entities affiliated with BVF Partners L.P., a holder of more than 5% of our capital stock, which we refer to as the BVF Notes. The BVF Notes accrued interest at the rate of 1.21% per annum and had a maturity date of May 2, 2020.

In March and June 2020, we completed three closings of an aggregate of 11,439,547 shares of our Series B convertible preferred stock at a purchase price of $4.712 per share.

The following table summarizes purchases of shares of our Series B convertible preferred stock by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

Participants[1]	Shares of Series B convertible preferred stock purchased for cash (#)	Shares of Series B convertible preferred stock issued upon conversion of BVF Notes (#)	Aggregate purchase price
Entities affiliated with BVF Partners L.P.	1,059,619[2]	638,270[3]	$ 8,000,000
Entities affiliated with Cormorant Asset Management, LP[4]	2,122,367	—	$ 10,000,000
Entities managed by Janus Capital Management LLC[5]	2,175,425	—	$ 10,250,000
Entities affiliated with RA Capital Management, L.P.[6]	1,273,419	—	$ 6,000,000
Logos Opportunities Fund I L.P.	1,400,761	—	$ 6,600,001
Wellington Biomedical Innovation Master Investors (Cayman) I L.P.	1,273,420	—	$ 6,000,000

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the section titled “Principal Stockholders.”

(2) Consists of (i) 545,678 shares of Series B convertible preferred stock purchased by BVF, (ii) 406,759 shares of Series B convertible preferred stock purchased by BVF2, (iii) 73,544 shares of Series B convertible preferred stock purchased by Trading Fund OS, and (iv) 33,638 shares of Series B convertible preferred stock purchased by a certain BVF Partners L.P. managed account. Dr. Hrustanovic, a member of our board of directors, is a Principal of BVF Partners L.P.

(3) Consists of (i) 343,508 shares of Series B convertible preferred stock issued to BVF, (ii) 266,522 shares of Series B convertible preferred stock issued to BVF2, and (iii) 28,240 shares of series B convertible preferred stock issued to Trading Fund OS.

(4) Consists of (i) 1,684,920 shares of Series B convertible preferred stock purchased by Cormorant Private Healthcare Fund II LP, (ii) 412,342 shares of Series B convertible preferred stock purchased by Cormorant Master Fund, and (iii) 25,105 shares of Series B convertible preferred stock purchased by CRMA.

(5) Janus Capital is an independent investment advisor registered under the Investment Advisers Act of 1940. Shares held by entities for whom Janus Capital is the investment advisor and who are holding our securities are aggregated for purposes of reporting share ownership information, including (i) 1,096,377 shares of Series B convertible preferred stock purchased by Janus Global Fund, (ii) 708,388 shares of Series B convertible preferred stock purchased by Janus Capital Funds, and (iii) 370,660 shares of Series B convertible preferred stock purchased by Janus Henderson Biotech Innovation Master Fund Limited.

(6) Consists of (i) 851,582 shares of Series B convertible preferred stock purchased by RA Capital Healthcare Fund, L.P., (ii) 318,355 shares of Series B convertible preferred stock purchased by RA Capital Nexus Fund, L.P., and (iii) 103,482 shares of Series B convertible preferred stock purchased by Blackwell Partners LLC—Series A.

2017 and 2018 convertible notes

From April 2017 through April 2018, we issued convertible promissory notes in the aggregate principal amount of $1.0 million, which we refer to as the A-1 Notes. The A-1 Notes accrued interest at the rate of 6% per annum and provided that in the event of a qualified equity financing in an amount not less than $3 million, the A-1 Notes would automatically convert into shares of our convertible preferred stock and common stock. The A-1 Notes converted into 516,249 shares of Series A-1 convertible preferred stock and 129,099 shares of common stock in July 2018.

The following table summarizes aggregate principal amount of A-1 Notes issued to holders of more than 5% of our capital stock, our directors and executive officers and entities affiliated with our executive officers and members of our board of directors.

Noteholder[1]	Aggregate principal amount
Peter J. Kushner, Ph.D.	$ 254,056
Frank McCormick, Ph.D., F.R.S., D.Sc. (Hon)	$ 300,000
SPW Investments LLC[2]	$ 252,625

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the section titled “Principal Stockholders.”

(2) Mr. Rappaport, one of our directors, is a managing member of Skyline Public Works, LLC, which is the general partner of SPW Investments LLC.

Series A-1 convertible preferred stock financing

In July 2018, we completed the closing of an aggregate of 2,963,906 shares of our Series A-1 convertible preferred stock, which includes the shares issued upon conversion of the A-1 Notes, at a purchase price of $2.043 per share.

The following table summarizes purchases of shares of our Series A-1 convertible preferred stock by holders of more than 5% of our capital stock, our directors and executive officers and entities affiliated with our executive officers and members of our board of directors.

Participants[1]	Shares of Series A-1 convertible preferred stock purchased for cash (#)	Shares of Series A-1 convertible preferred stock issued upon conversion of A-1 Notes (#)	Shares of common stock issued upon conversion of A-1 Notes (#)	Aggregate purchase price
Entities affiliated with BVF Partners L.P.[2]	2,447,657		—	$ 5,000,000
Peter J. Kushner, Ph.D.	—	130,159	32,580	$ 266,226
Frank McCormick, Ph.D., F.R.S., D.Sc. (Hon)	—	152,891	38,222	$ 312,322
SPW Investments LLC[3]	—	129,833	32,458	$ 265,221

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the caption "Principal Stockholders."

(2) Consists of (i) 1,129,404 shares of Series A-1 convertible preferred stock purchased by BVF, (ii) 881,156 shares of Series A-1 convertible preferred stock purchased by BVF2, (iii) 185,908 shares of Series A-1 convertible preferred stock purchased by Trading Fund OS and (iv) 251,189 shares of Series A-1 convertible preferred stock purchased by certain BVF Partners L.P. managed accounts. Dr. Hrustanovic, a member of our board of directors, is a Principal of BVF Partners L.P.

(3) Mr. Rappaport, one of our directors, is a managing member of Skyline Public Works, LLC, which is the general partner of SPW Investments LLC.

Employment agreements and stock option grants to directors and executive officers

We have entered into employment agreements with certain of our named executive officers, and granted stock options to our named executive officers and certain of our directors, as more fully described in the sections titled "Executive Compensation" and "Management—Non-Employee Director Compensation."

Investors' rights agreement

In September 2020, we entered into an Amended and Restated Investors' Rights Agreement, or the Rights Agreement, with certain holders of more than 5% of our outstanding capital stock, including entities affiliated with BVF Partners L.P., entities affiliated with Cormorant Asset Management, LP, entities managed by Janus Capital Management LLC, entities affiliated with Logos Opportunities Fund I L.P., entities affiliated with RA Capital Management, L.P. and Wellington Biomedical Innovation Master Investors (Cayman) I L.P., and including certain affiliates of our directors.

The Rights Agreement grants to the holders of our outstanding convertible preferred stock certain rights, including certain registration rights with respect to the registrable securities held by them. See the section titled "Description of Capital Stock—Registration Rights" for additional information. In addition, the Rights Agreement imposes certain affirmative obligations on us, including our obligation to, among other things, (i) grant each holder who holds at least 179,340 shares of our convertible preferred stock, or the Major Investors, a right of first offer with respect to future sales of our equity, excluding the shares to be offered and sold in this offering. The Rights Agreement also grants certain information and inspection rights to such Major Investors and certain holders of our outstanding convertible preferred stock upon request. Each of these obligations will terminate in connection with the closing of this offering.

Voting agreement

In September 2020, we entered into an Amended and Restated Voting Agreement, or the Voting Agreement, with certain holders of more than 5% of our outstanding capital stock, including entities affiliated with BVF Partners L.P.,

entities affiliated with Cormorant Asset Management, LP, entities managed by Janus Capital Management LLC, entities affiliated with Logos Opportunities Fund I L.P., entities affiliated with RA Capital Management, L.P. and Wellington Biomedical Innovation Master Investors (Cayman) I L.P., and including certain affiliates of our directors.

Pursuant to the Voting Agreement, each of BVF Partners LP and Logos Global Management LP have the right to designate one member to be elected to our board of directors, and BVF Partners LP, Logos Global Management LP and Janus Capital Management LLC, collectively, have the right to designate one director. See the section titled "Management—Composition of Our Board of Directors." The Voting Agreement will terminate by its terms in connection with the closing of this offering and none of our stockholders will have any continuing rights regarding the election or designation of members of our board of directors following this offering.

Right of first refusal and co-sale agreement

In September 2020, we entered into an Amended and Restated Right of First Refusal and Co-Sale Agreement, or the Co-Sale Agreement, with certain holders of more than 5% of our outstanding capital stock, including entities affiliated with BVF Partners L.P., entities affiliated with Cormorant Asset Management, LP, entities managed by Janus Capital Management LLC, entities affiliated with Logos Opportunities Fund I L.P., entities affiliated with RA Capital Management, L.P. and Wellington Biomedical Innovation Master Investors (Cayman) I L.P., and including certain affiliates of our directors.

Pursuant to the Co-Sale Agreement, we have a right of first refusal in respect of certain sales of securities by certain holders of our common stock and convertible preferred stock. To the extent we do not exercise such right in full, the Major Investors are granted certain rights of first refusal and co-sale in respect of such sale. The Co-Sale Agreement will terminate in connection with the closing of this offering.

Directed Share Program

At our request, the underwriters have reserved up to 5% of the shares offered by this prospectus for sale at the initial public offering price to certain individuals through a directed share program, including our directors, officers, employees and certain other individuals identified by management.

Indemnification agreements

Our amended and restated certificate of incorporation will contain provisions limiting the liability of directors, and our amended and restated bylaws will provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by the board. In addition, we have entered into or intend to enter into an indemnification agreement with each of our directors and executive officers, which will require us to indemnify them. For more information regarding these agreements, see the section titled "Executive Compensation—Limitations on Liability and Indemnification."

Policies and procedures for transactions with related persons

In connection with this offering, we adopted a written policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the approval or ratification of our board of directors or our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds $120,000 and such person would have a direct or indirect interest, must be presented to our board of directors or our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our board of directors or our audit committee is to consider the material facts of the transaction, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

Principal stockholders

The following table sets forth information regarding beneficial ownership of our capital stock as of November 1, 2020 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each our of named executive officers; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership before the offering is based on 27,519,738 shares of our common stock outstanding as of November 1, 2020, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 23,765,075 shares of our common stock in connection with the closing of this offering and including 895,391 shares of our unvested restricted common stock subject to repurchase as of such date.

Applicable percentage ownership after the offering is based on 38,519,738 shares of common stock outstanding immediately after the closing of this offering, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock in connection with the closing of this offering and including 895,391 shares of our unvested restricted common stock subject to repurchase as of November 1, 2020. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares subject to options held by the person that are currently exercisable, or exercisable within 60 days of November 1, 2020. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person. The table below excludes any purchases that may be made through our directed share program and any potential purchases in this offering by the beneficial owners identified in the table below.

Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o Olema Pharmaceuticals, Inc., 512 2nd Street, 4th Floor, San Francisco, CA 94107.

Name of beneficial owner	Number of shares beneficially owned (#)	Percentage of shares beneficially owned	
		Before offering (%)	After offering (%)
Greater than 5% Holders:			
Entities affiliated with BVF Partners L.P.[1]	5,501,503	20.0	14.3
Entities affiliated with Cormorant Asset Management, LP[2]	2,845,544	10.3	7.4
Entities managed by Janus Capital Management LLC[3]	2,916,681	10.6	7.6
Entities affiliated with Logos Opportunities Fund I L.P.[4]	2,583,875	9.4	6.7
Entities affiliated with RA Capital Management, L.P.[5]	1,725,404	6.3	4.5
Wellington Biomedical Innovation Master Investors (Cayman) I L.P.[6]	1,725,406	6.3	4.5
Directors and Named Executive Officers:			
Cyrus L. Harmon, Ph.D.[7]	1,247,815	4.5	3.2
Peter J. Kushner, Ph.D.[8]	1,431,672	5.2	3.7
David C. Myles, Ph.D.[9]	759,498	2.8	2.0
Sean Bohen, M.D., Ph.D.[10]	1,027,965	3.6	2.6
Andrew Rappaport[11]	573,846	2.1	1.5
Cynthia Butitta[12]	83,876	*	*
Ian Clark[13]	209,690	*	*
Sandra Horning, M.D.	—	*	*
Gorjan Hrustanovic, Ph.D.	—	*	*
Frank McCormick, Ph.D., F.R.S., D.Sc. (Hon)[14]	350,271	1.3	*
Graham Walmsley, M.D., Ph.D.[15]	2,583,875	9.4	6.7
All directors and executive officers as a group (14 persons)[16]	8,910,756	30.5	22.2

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 1,129,404 shares of common stock issuable upon conversion of the Series A-1 convertible preferred stock held by Biotechnology Value Fund L.P., or BVF, (ii) 889,186 shares of common stock issuable upon conversion of the Series B convertible preferred stock held by BVF, (iii) 760,155 shares of common stock issuable upon conversion of the Series C convertible preferred stock held by BVF, (iv) 881,156 shares of common stock issuable upon conversion of the Series A-1 convertible preferred stock held by Biotechnology Value Fund II, L.P., or BVF2, (v) 673,281 shares of common stock issuable upon conversion of the Series B convertible preferred stock held by BVF2, (vi) 522,403 shares of common stock issuable upon conversion of the Series C convertible preferred stock held by BVF2, (vii) 185,908 shares of common stock issuable upon conversion of the Series A-1 convertible preferred stock held by Biotechnology Value Trading Fund OS L.P., or Trading Fund OS, (viii) 101,784 shares of common stock issuable upon conversion of the Series B convertible preferred stock held by Trading Fund OS, (ix) 73,399 shares of common stock issuable upon conversion of the Series C convertible preferred stock held by Trading Fund OS, (x) 251,189 shares of common stock issuable upon conversion of the Series A-1 convertible preferred stock held by certain BVF Partners L.P. managed accounts, or Partners Managed Accounts and (xi) 33,638 shares of common stock issuable upon conversion of the Series B convertible preferred stock held by Partners Managed Accounts. BVF I GP L.L.C., or BVF GP, as the general partner of BVF, may be deemed to beneficially own the shares beneficially owned by BVF. BVF II GP L.L.C., or BVF2 GP, as the general partner of BVF2, may be deemed to beneficially own the shares beneficially owned by BVF2. BVF Partners OS Ltd., or Partners OS, as the general partner of Trading Fund OS, may be deemed to beneficially own the beneficially owned by Trading Fund OS. BVF GP Holdings L.L.C., or BVF GPH, as the sole member of each of BVF GP and BVF2 GP, may be deemed to beneficially own the shares beneficially owned in the aggregate by BVF and BVF2. BVF Partners L.P., or Partners, as the general partner of BVF, BVF2, the investment manager of Trading Fund OS, and the sole member of Partners OS, may be deemed to beneficially own the shares beneficially owned by BVF, BVF2, Trading Fund OS and Partners Managed Accounts. BVF, Inc., as the general partner of Partners, may be deemed to beneficially own the shares beneficially owned by Partners. Mark Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the shares beneficially owned by BVF Inc. The address of BVF Partners L.P. is 44 Montgomery St. 40th floor, San Francisco, California 94104.

(2) Consists of (i) 412,342 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by Cormorant Global Healthcare Master Fund , LP, or Cormorant Master Fund, (ii) 126,122 shares of common stock issuable upon conversion of the Series C convertible preferred stock held by Cormorant Master Fund, (iii) 1,684,920 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by Cormorant Private Healthcare Fund II LP, or Cormorant Fund II, (iv) 587,871 shares of common stock issuable upon conversion of the Series C convertible preferred stock held by Cormorant Private Healthcare Fund III, LP, or Cormorant Fund III, (v) 25,105 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by CRMA, SPV L.P., or CRMA, and (vi) 9,184 shares of common stock issuable upon conversion of the Series C convertible preferred stock held by CRMA. Cormorant Global Healthcare GP, LLC, or Global

GP, is the general partner of Cormorant Master Fund, Cormorant Private Healthcare II GP, LLC, or Private GP II, is the general partner of Cormorant Fund II, and Cormorant Private Healthcare III GP, LLC, or Private GP III, is the general partner of Cormorant Fund III. Bihua Chen serves as the managing member of Global GP, Private GP II, and Private GP III, and as the general partner of Cormorant Asset Management, LP, or Cormorant. Cormorant serves as the investment manager to Cormorant Fund II, Cormorant Fund III, Cormorant Master Fund and CRMA. Ms. Chen has sole voting and investment control over the shares held by the Cormorant Master Fund, Cormorant Fund II and CRMA. The address for each of the entities is 200 Clarendon Street, 52nd Floor, Boston Massachusetts 02116.

(3) Consists of (i) 370,660 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by Janus Henderson Biotech Innovation Master Fund Limited, or Janus Biotech, (ii) 708,388 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by Janus Henderson Capital Funds PLC on behalf of its series Janus Henderson Global Life Sciences Fund, or Janus Capital Funds, (iii) 354,859 shares of common stock issuable upon conversion of the Series C convertible preferred stock held by Janus Capital Funds, (iv) 1,096,377 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by Janus Henderson Global Life Sciences Fund, or Janus Global Fund, (v) 379,331 shares of common stock issuable upon conversion of the Series C convertible preferred stock held by Janus Global Fund, and (vi) 7,066 shares of common stock issuable upon conversion of the Series C convertible preferred stock held by Janus Henderson Horizon Fund - Biotechnology Fund, or Janus Horizon. Janus Capital Management LLC, or Janus Capital, is the investment adviser to Janus Biotech, Janus Capital Funds, Janus Global Fund and Janus Horizon. The portfolio manager for each of Janus Global Fund and Janus Capital Funds is Andrew Acker, and the portfolio managers for Janus Biotech and Janus Horizon are Andrew Acker and Dan Lyons. Janus Capital, Andrew Acker and Dan Lyons may be deemed to have voting and dispositive power over the shares held by Janus Biotech and Janus Horizon. The address of the principal business office of each of the foregoing entities is c/o Janus Capital Management LLC, 151 Detroit Street, Denver, Colorado 80206.

(4) Consists of (i) 1,400,761 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by Logos Opportunities Fund I L.P., or Logos Fund I, and (ii) 1,183,114 shares of common stock issuable upon the conversion of Series C convertible preferred stock held by Logos Opportunities Fund II, L.P., or Logos Fund II. Logos Opportunities GP, LLC, or Logos GP, is the general partner of Logos Fund I and Logos Fund II. Dr. Arsani William and Dr. Graham Walmsley are the managing members of Logos GP and share voting and dispositive power with respect to the shares held of record by Logos Fund I and Logos Fund II. The address for these entities is c/o Logos Global Management, LP, 1 Letterman Drive, Building D, Suite D3-700, San Francisco, California 94129.

(5) Consists of (i) 851,582 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by RA Capital Healthcare Fund, L.P., or RA Healthcare, (ii) 307,739 shares of common stock issuable upon conversion of the Series C convertible preferred stock held by RA Healthcare, (iii) 318,355 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by RA Capital Nexus Fund, L.P., or RA Nexus, (iv) 112,996 shares of common stock issuable upon conversion of the Series C convertible preferred stock held by RA Nexus, (v) 103,482 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by Blackwell Partners LLC—Series A, or Blackwell and (vi) 31,250 shares of common stock issuable upon conversion of the Series C convertible preferred stock held by Blackwell. RA Capital Management, L.P., or RA Management, is the investment manager for RA Healthcare, RA Nexus and Blackwell. The general partner of RA Management is RA Capital Management GP, LLC, or RA GP, of which Peter Kolchinsky and Rajeev Shah are managing members. RA Management, RA GP, Peter Kolchinsky and Rajeev Shah may be deemed to have voting and investment power over the shares held of record by RA Healthcare, RA Nexus and Blackwell. The address of the entities listed above is 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.

(6) Consists of (i) 1,273,420 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by Wellington Biomedical Innovation Master Investors (Cayman) I L.P., or Wellington Biomedical and (ii) 451,986 shares of common stock issuable upon conversion of the Series C convertible preferred stock held by Wellington Biomedical. Wellington Management Company LLP, a registered investment advisor under the Investment Advisers Act of 1940, as amended, is the investment advisor to Wellington Biomedical, and Wellington Alternative Investments LLC is its general partner. Wellington Management Investment, Inc. is the managing member of Wellington Alternative Investments LLC. Wellington Management Company LLP is an indirect subsidiary of Wellington Management Group LLP. Wellington Management Group LLP and Wellington Management Company LLP may be deemed beneficial owners with shared voting and investment power over the shares held by Wellington Biomedical. The address for Wellington Biomedical and the Wellington entities is 280 Congress Street, Boston, Massachusetts 02210.

(7) Consists of (i) 1,040,172 shares of common stock held directly by Dr. Harmon, (ii) 71,374 shares of common stock issuable upon the conversion of Series A convertible preferred stock held directly by Dr. Harmon, (iii) 122,028 shares of common stock issuable upon the conversion of Series A convertible preferred stock held by Harmon Family Investors LLC, over which Dr. Harmon holds voting and investment power as manager, and (iv) 14,241 shares of common stock issuable upon exercise of stock options held by Dr. Harmon that are exercisable within 60 days of November 1, 2020.

(8) Consists of (i) 1,072,752 shares of common stock, (ii) 228,761 shares of common stock issuable upon the conversion of Series A convertible preferred stock, and (iii) 130,159 shares of common stock issuable upon the conversion of Series A-1 convertible preferred stock.

(9) Consists of (i) 591,821 shares of common stock held directly by Dr. Myles, (ii) 12,831 shares of common stock issuable upon the conversion of Series A convertible preferred stock held by The Myles Family Revocable Inter Vivos Trust, over which Dr. Myles holds voting and investment power as trustee, and (iii) 154,846 shares of common stock issuable upon the conversion of Series A convertible preferred stock held by Myles Properties Inc., over which Dr. Myles holds voting and investment power as President.

(10) Consists of (i) 51,649 shares of common stock and (ii) 976,316 shares of common stock issuable upon exercise of stock options held by Dr. Bohen that are exercisable within 60 days of November 1, 2020.

(11) Consists of (i) 32,458 shares of common stock held by SPW Investments LLC, or SPWI, (ii) 318,723 shares of common stock issuable upon the conversion of Series A convertible preferred stock held by SPWI, (iii) 129,833 shares of common stock issuable upon the conversion of Series A-1 convertible preferred stock held by SPWI, and (iv) 92,832 shares of common stock issuable upon exercise of stock options held by Mr. Rappaport that are exercisable within 60 days of November 1, 2020. Mr. Rappaport is a managing member of Skyline Public Works, LLC, which is the general partner of SPWI, and in such capacity shares voting and dispositive power with respect to the shares held by SPWI.

(12) Consists of 83,876 shares of common stock.

(13) Consists of 209,690 shares of common stock issuable upon exercise of stock options held by Mr. Clark that are exercisable within 60 days of November 1, 2020.

(14) Consists of (i) 38,222 shares of common stock held directly by Dr. McCormick, (ii) 152,891 shares of common stock issuable upon the conversion of Series A-1 convertible preferred stock held directly by Dr. McCormick, (iii) 17,934 shares of common stock held by the Francis P. McCormick Revocable Trust dated January 27, 2017, (iv) 66,326 shares of common stock issuable upon the conversion of Series A convertible preferred stock held by the Francis P. McCormick Revocable Trust dated January 27, 2017, and (v) 74,898 shares of common stock issuable upon exercise of

stock options held by Dr. McCormick that are exercisable within 60 days of November 1, 2020. Dr. McCormick holds voting and investment power over the shares held by the trustee of Francis P. McCormick Revocable Trust dated January 27, 2017.

(15) Consists of shares held by Logos Fund I and Logos Fund II disclosed in footnote 5 above. Dr. Walmsley is a managing member of Logos GP and shares voting and dispositive power with respect to the shares held by Logos Fund I and Logos Fund II.

(16) Consists of (i) 3,287,564 shares of common stock held by our current directors and executive officers as a group, (ii) 974,889 shares of common stock issuable upon the conversion of Series A convertible preferred stock held by our current directors and executive officers as a group, (iii) 412,883 shares of common stock issuable upon the conversion of Series A-1 convertible preferred stock held by our current directors and executive officers as a group, (iv) 1,400,761 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by our current directors and executive officers as a group, (v) 1,183,114 shares of common stock issuable upon the conversion of Series C convertible preferred stock held by our current directors and executive officers as a group, and (vi) 1,651,545 shares of common stock issuable upon the exercise of stock options held by our current directors and executive officers that are exercisable within 60 days of November 1, 2020.

Description of capital stock

General

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation, which will become effective immediately after the closing of this offering, and the amended and restated bylaws, which will become effective upon the closing of this offering. Copies of these documents have been filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will be in effect on the closing of this offering.

Upon filing of our amended and restated certificate of incorporation and the closing of this offering, our authorized capital stock will consist of 490,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share. All of our authorized shares of preferred stock will be undesignated.

As of September 30, 2020, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 23,765,075 shares of our common stock in connection with the closing of this offering and including 895,391 shares of our unvested restricted common stock subject to repurchase as of such date, there were 27,519,738 shares of common stock outstanding and held of record by 84 stockholders.

Common stock

Voting rights

The common stock is entitled to one vote per share on any matter that is submitted to a vote of our stockholders. Our amended and restated certificate of incorporation does not provide for cumulative voting for the election of directors. Our amended and restated certificate of incorporation establishes a classified board of directors that is divided into three classes with staggered three-year terms. Only the directors in one class will be subject to election by a plurality of the votes cast at each annual meeting of our stockholders, with the directors in the other classes continuing for the remainder of their respective three-year terms. The affirmative vote of holders of at least 66 ⅔% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified structure of our board of directors, the size of our board of directors, removal of directors, director liability, vacancies on our board of directors, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

Economic rights

Except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law, all shares of common stock will have the same rights and privileges and rank equally, share ratably, and be identical in all respects for all matters, including those described below.

Dividends. 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. See the section titled “Dividend Policy” for further information.

Liquidation rights. On our liquidation, dissolution, or winding-up, the holders of common stock will be entitled to share equally, identically, and ratably in all assets remaining after the payment of any liabilities, liquidation preferences and accrued or declared but unpaid dividends, if any, with respect to any outstanding preferred stock, unless a different treatment is approved by the affirmative vote of the holders of a majority of the outstanding shares of such affected class, voting separately as a class.

No preemptive or similar rights

The holders of our shares of common stock are not entitled to preemptive rights, and are not subject to conversion, redemption or sinking fund provisions.

Fully paid and non-assessable

In connection with this offering, our legal counsel will opine that the shares of our common stock to be issued under this offering will be fully paid and non-assessable.

Preferred stock

Upon the closing of this offering, all of our currently outstanding shares of convertible preferred stock will convert into common stock and we will not have any convertible preferred stock outstanding. Immediately after the closing of this offering, our certificate of incorporation will be amended and restated to delete all references to such shares of convertible preferred stock. Under the amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Stock options

As of September 30, 2020, 2,505,811 shares of common stock were issuable upon the exercise of outstanding stock options, at a weighted-average exercise price of $4.14 per share. For additional information regarding terms of our equity incentive plans, see the section titled “Executive Compensation—Equity Benefit Plans.”

Registration rights

Upon the closing of this offering and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, certain holders of shares of our common stock, including those shares of our common stock that will be issued upon the conversion of our convertible preferred stock in connection with this offering, will initially be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our Rights Agreement and are described in additional detail below. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will expire no later than three years after the closing of this offering, or with respect to any particular holder, at such time that such holder can sell its shares under Rule 144 of the Securities Act during any three-month period.

Demand registration rights

Upon the closing of this offering, holders of an aggregate of approximately 23.7 million shares of our common stock will be entitled to certain demand registration rights. At any time beginning 180 days after the closing of this offering, the holders of 30% of these shares may request that we register all or a portion of their shares. We are not required to effect more than two registration statements which are declared or ordered effective. Such request for registration must cover shares with an anticipated aggregate offering price, net of expenses, of at least $10 million. With certain exceptions, we are not required to effect the filing of a registration statement during the period starting with the date of the filing of, and ending on a date 180 days following the effective date of the registration statement for this offering.

Piggyback registration rights

In connection with this offering, the holders of an aggregate of approximately 23.7 million shares of our common stock were entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their shares of registrable securities in this offering. After this offering, in the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the holders of these shares will be entitled to certain piggyback registration rights allowing the holder to include their shares in such registration, subject to certain marketing and other limitations.

Form S-3 registration rights

Upon the closing of this offering, holders of an aggregate of approximately 23.7 million shares of common stock will be entitled to certain Form S-3 registration rights. Holders of 30% of these shares can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3 and if the anticipated aggregate offering price, net of expenses, would equal or exceed $2 million. We will not be required to effect more than two registrations on Form S-3 within any 12-month period.

Anti-takeover provisions

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws, which are summarized below, may have the effect of delaying, deferring or discouraging another person from acquiring control of our company. 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.

Certificate of incorporation and bylaws to be in effect in connection with this offering

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock will be able to elect all of our directors. Our amended and restated certificate of incorporation, to be effective immediately after the closing of this offering, and our amended and restated bylaws, to be effective on the closing of this offering, will provide for stockholder actions at a duly called meeting of stockholders or, before the date on which all shares of common stock convert into a single class, by written consent. A special meeting of stockholders may be called by a majority of our board of directors, the chair of our board of directors, or our chief executive officer or president. Our amended and restated bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors.

As described above in “Management—Composition of Our Board of Directors,” in accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms.

The foregoing provisions will make it more difficult for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Section 203 of the Delaware general corporation law

When we have a class of voting stock that is either listed on a national securities exchange or held of record by more than 2,000 stockholders, we will be subject to Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, subject to certain exceptions.

Choice of forum

Our amended and restated certificate of incorporation to be effective immediately after the closing of this offering will provide that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (iii) any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, or our bylaws (as each may be amended from time to time); (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us or any of our current or former directors, officers, or other employees governed by the internal-affairs doctrine or otherwise related to our internal affairs, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. This choice of forum provision would not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation to be effective on the closing of this offering will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Additionally, our amended and restated certificate of incorporation to be effective immediately after the closing of this offering will provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

Limitations on liability and indemnification

See the section titled “Executive Compensation—Limitations on Liability and Indemnification.”

Exchange listing

Our common stock is currently not listed on any securities exchange. Our common stock has been approved for listing on The Nasdaq Global Select Market under the symbol “OLMA.”

Transfer agent and registrar

On the closing of this offering, the transfer agent and registrar for our common stock will be Computershare Trust Company, N.A.

Shares eligible for future sale

Before the closing of this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock, including shares issued on the exercise of outstanding options, in the public market after this offering, or the possibility of these sales or issuances occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital.

Based on our shares outstanding as of September 30, 2020, upon the closing of this offering, a total of 38,519,738 shares of common stock will be outstanding, assuming the automatic conversion of all outstanding shares of our convertible preferred stock into 23,765,075 shares of our common stock in connection with the closing of this offering and 895,391 shares of unvested restricted common stock subject to repurchase. Of these shares, all of the common stock sold in this offering by us, plus any shares sold by us on exercise of the underwriters' option to purchase additional common stock, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by "affiliates," as that term is defined in Rule 144 under the Securities Act, or Rule 144.

The remaining shares of common stock will be, and shares of common stock subject to stock options will be on issuance, "restricted securities," as that term is defined in Rule 144. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. Restricted securities may also be sold outside of the United States to non-U.S. persons in accordance with Rule 904 of Regulation S.

Subject to the lock-up agreements described below and the provisions of Rule 144 or Regulation S under the Securities Act, as well as our insider trading policy, these restricted securities will be available for sale in the public market after the date of this prospectus.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described below.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements described below. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately 385,197 shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares of common stock from us; or
- the average weekly trading volume of our common stock on The Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 of the Securities Act, or Rule 701, generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below.

Form S-8 registration statements

We intend to file one or more registration statements on Form S-8 under the Securities Act with the SEC to register the offer and sale of shares of our common stock that are issuable under our 2014 Plan, 2020 Plan and ESPP. These registration statements will become effective immediately on filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below, and Rule 144 limitations applicable to affiliates.

Lock-up arrangements

We, and all of our directors, executive officers and the holders of substantially all of our common stock and securities exercisable for or convertible into our common stock outstanding immediately on the closing of this offering, have agreed with the underwriters that, until 180 days after the date of the underwriting agreement related to this offering, we and they will not, without the prior written consent of the representatives of the underwriters, subject to certain exceptions, directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any of our shares of common stock, or any securities convertible into or exercisable or exchangeable for shares of our common stock, or enter into any hedging, swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the securities, whether any such swap or transaction is to be settled by delivery of our common stock or other securities, in cash or otherwise. These agreements are described in “Underwriting.” The representatives of the underwriters may, in their sole discretion, release any of the securities subject to these lock-up agreements at any time.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain security holders, including the Rights Agreement, our standard form of option agreement and our standard form of restricted stock agreement, that contain market stand-off provisions or incorporate market stand-off provisions from our equity incentive plan imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

Registration rights

Upon the closing of this offering, pursuant to our Rights Agreement, the holders of approximately 23.7 million shares of our common stock, or their transferees, will be entitled to certain rights with respect to the registration of the offer and sale of their shares under the Securities Act, subject to the terms of the lock-up agreements described under the section titled “—Lock-Up Arrangements” above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately on the effectiveness of the registration. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See the section titled “Description of Capital Stock—Registration Rights” for additional information.

Certain material U.S. federal income tax consequences to non-U.S. holders

The following is a summary of certain material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, and does not address any estate or gift tax consequences or any tax consequences arising under any state, local or foreign tax laws, or any other U.S. federal tax laws. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the Internal Revenue Service, or the IRS, all as in effect on the date of this prospectus. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to an individual non-U.S. holder in light of such non-U.S. holder's particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to non-U.S. holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other pass-through entities (and investors therein);
- "controlled foreign corporations";
- "passive foreign investment companies";
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers or traders in securities;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons who acquire our common stock through the exercise of an option or otherwise as compensation;
- qualified foreign pension funds as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons subject to the alternative minimum tax;
- persons subject to special tax accounting rules under Section 451(b) of the Code;
- persons that own or have owned, actually or constructively, more than 5% of our common stock;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.

Definition of non-U.S. holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is not a "U.S. holder" or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. holder is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

Distributions on our common stock

As described under the section titled "Dividend Policy," we do not anticipate declaring or paying, in the foreseeable future, any cash distributions on our capital stock. However, if we distribute cash or other property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's tax basis in our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under the section titled "—Gain on Disposition of Our Common Stock" below.

Subject to the discussion below regarding effectively connected income, backup withholding and FATCA (as defined below), dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our withholding agent with a valid IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying such holder's qualification for the reduced rate. This certification must be provided to us or our withholding agent before the payment of dividends and must be updated periodically. In the case of a non-U.S. Holder that is an entity, Treasury Regulations and the relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of the tax treaty, dividends will be treated as paid to the entity or to those holding an interest in the entity. If the non-U.S. holder holds our common stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our withholding agent, either directly or through other intermediaries.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder's U.S. trade or business (and are attributable to such holder's permanent establishment or fixed base in the United States if required by an applicable tax treaty), the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent.

However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on disposition of our common stock

Subject to the discussion below regarding backup withholding and FATCA (as defined below), a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a "United States real property interest" by reason of our status as a United States real property holding corporation, or a USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock, and our common stock is not regularly traded on an established securities market during the calendar year in which the sale or other disposition occurs.

Determining whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests. We believe that we are not currently and we do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. Gain described in the third bullet point above will generally be subject to U.S. federal income tax in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply.

Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information reporting and backup withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of dividends on our common stock paid to such holder and the amount of any tax withheld with respect to those dividends. These information reporting requirements apply even if no withholding was required because the dividends were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was

reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or certain other requirements are met, and if the payor does not have actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

Withholding on foreign entities

Sections 1471 through 1474 of the Code, which are commonly referred to as FATCA, impose a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our common stock and would have applied also to payments of gross proceeds from the sale or other disposition of our common stock. The U.S. Treasury Department has released proposed regulations under FATCA providing for the elimination of the federal withholding tax of 30% applicable to gross proceeds of a sale or other disposition of our common stock. Under these proposed Treasury Regulations (which may be relied upon by taxpayers prior to finalization), FATCA will not apply to gross proceeds from sales or other dispositions of our common stock.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

Underwriting

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of Shares
J.P. Morgan Securities LLC	4,510,000
Jefferies LLC	3,080,000
Cowen and Company, LLC	2,640,000
Canaccord Genuity LLC	770,000
Total	11,000,000

The underwriters are committed to purchase all the common shares offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the shares of common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $0.798 per share. After the initial offering of the shares to the public, if all of the shares of common stock are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to 1,650,000 additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is $1.33 per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without option to purchase additional shares exercise	With full option to purchase additional shares exercise
Per Share	$ 1.33	$ 1.33
Total	$14,630,000.00	$16,824,500.00

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately $3.28 million. We have agreed to reimburse the underwriters for expenses of up to $40,000 relating to the clearance of this offering with the Financial Industry Regulatory Authority.

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exercisable or exchangeable for any shares of our common stock, or publicly disclose the intention to undertake any of the foregoing, or (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences associated with the ownership of any shares of common stock or any such other securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of common stock or such other securities, in cash or otherwise, in each case without the prior written consent of J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC for a period of 180 days after the date of this prospectus, other than the shares of our common stock to be sold in this offering.

The restrictions on our actions, as described above, do not apply to certain transactions, including (i) the issuance of shares of common stock or securities convertible into or exercisable for shares of our common stock pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options (including net exercise) or the settlement of restricted stock units (“RSUs”) (including net settlement), in each case outstanding on the date of the underwriting agreement and described in this prospectus; (ii) grants of stock options, stock awards, restricted stock, RSUs, or other equity awards and the issuance of shares of our common stock or securities convertible into or exercisable or exchangeable for shares of our common stock (whether upon the exercise of stock options or otherwise) to the company’s employees, officers, directors, advisors, or consultants pursuant to the terms of an equity compensation plan in effect as of the closing of this offering and described in this prospectus; or (iii) the issuance of up to 5% of our securities outstanding immediately following the consummation of this offering in connection with mergers, acquisitions, joint ventures or commercial or strategic transactions; provided that the recipient of any such shares of our common stock or securities enter into a lock-up agreement with the underwriters.

Our directors, executive officers, and substantially all of our shareholders (such persons, the “lock-up parties”) have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of 180 days after the date of this prospectus (such period, the “restricted period”), may not (and may not cause any of their direct or indirect affiliates to), without the prior written consent of J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC, (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock (including without limitation, common stock or such other securities which may be deemed to be beneficially owned by such lock-up parties in accordance with the rules and regulations of the Securities and Exchange Commission and securities which may be issued upon exercise of a stock option or warrant) (collectively with the common stock, “Lock-Up Securities”), (2) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the Lock-Up Securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Lock-Up Securities, in cash or otherwise, (3) make any demand for or exercise any right with respect to the registration of any Lock-Up Securities, or (4) publicly disclose the intention to do any of the foregoing. Such persons or entities have further acknowledged that these undertakings preclude them from engaging in any hedging or other transactions or arrangements (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition or transfer (by any person or entity, whether or not a signatory to such agreement) of any Lock-Up

Securities, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of Lock-Up Securities, in cash or otherwise.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to certain transactions, including (a) transfers of lock-up securities: (i) as bona fide gifts, or for bona fide estate planning purposes, (ii) by will, other testamentary document or intestacy, (iii) to any trust for the direct or indirect benefit of the lock-up party or any immediate family member, or if the lock-up party is a trust, to a trustor or beneficiary of the trust or to the estate of a beneficiary of such trust (for purposes of the lock-up agreement, "immediate family" shall mean any relationship by blood, current or former marriage, domestic partnership or adoption, not more remote than first cousin), (iv) to a partnership, limited liability company or other entity of which the lock-up party or its immediate family members are the legal and beneficial owner of all of the outstanding equity securities or similar interests, (v) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (iv), (vi) in the case of a corporation, partnership, limited liability company, trust or other business entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate of the lock-up party, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the lock-up party or its affiliates, (including, for the avoidance of doubt, where the lock-up party is a partnership, to its general partner or a successor partnership or fund, or any other funds managed by such partnership) or (B) as part of a distribution, transfer or disposition without consideration by the lock-up party to members or stockholders, partners, members beneficiaries or other equity holders of the lock-up party; (vii) by operation of law, such as pursuant to a qualified domestic order, divorce settlement, divorce decree, separation agreement or other court order, (viii) to us (A) from an employee or other service provider upon death, disability or termination of employment or service, in each case of such employee or service provider or (B) pursuant to an agreement under which we have a right of first refusal with respect to transfers of the lock-up securities, (ix) as part of a sale of lock-up securities acquired in this offering (other than any Company-directed securities acquired in this offering by an executive officer or director) or in open market transactions after the closing of this offering, (x) to us in connection with the vesting, settlement or exercise of restricted stock units, options, warrants or other rights to purchase shares of our common stock (including "net" or "cashless" exercise), including for the payment of exercise price and tax and remittance payments due as a result of the vesting, settlement, or exercise of such restricted stock units, options, warrants or rights, provided that any such shares of common stock received upon such exercise, vesting or settlement shall be subject to the terms of the lock-up agreement, and provided further that any such restricted stock units, options, warrants or rights are held by the lock-up party pursuant to an agreement or equity awards granted under a stock incentive plan or other equity award plan, each such agreement or plan which is described in this registration statement, or (xi) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction approved by our board of directors and made to all stockholders involving a change in control, provided that if such transaction is not completed, all such lock-up securities would remain subject to the restrictions in the immediately preceding paragraph; (b) exercise of the options, settlement of RSUs or other equity awards, or the exercise of warrants granted pursuant to plans described in in the registration statement, the pricing disclosure package and this prospectus, provided that any lock-up securities received upon such exercise, vesting or settlement would be subject to restrictions similar to those in the immediately preceding paragraph; (c) the conversion of outstanding preferred stock, warrants to acquire preferred stock, or convertible securities into shares of our common stock or warrants to acquire shares of our common stock, provided that any common stock or warrant received upon such conversion would be subject to restrictions similar to those in the immediately preceding paragraph; and (d) the establishment by lock-up parties of trading plans under Rule 10b5-1 under the Exchange Act, provided that such plan does not provide for the transfer of lock-up securities during the restricted period.

J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC, in their sole discretion, may release the securities subject to any of the lock-up agreements with the underwriters described above, in whole or in part at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

Our common stock has been approved for listing on The Nasdaq Global Select Market under the symbol “OLMA.”

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be “covered” shorts, which are short positions in an amount not greater than the underwriters’ option to purchase additional shares referred to above, or may be “naked” shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on The Nasdaq Global Select Market, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters considered a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our common shares, or that the shares will trade in the public market at or above the initial public offering price.

Directed Share Program

At our request, the underwriters have reserved up to 5% of the shares offered by this prospectus for sale at the initial public offering price to certain individuals through a directed share program, including our directors, officers,

employees and certain other individuals identified by management. The sales will be made at our direction by J.P. Morgan Securities LLC and its affiliates through a directed share program. The number of shares of our common stock available for sale to the general public in this offering will be reduced to the extent that such persons purchase such reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of common stock offered by this prospectus. We have agreed to indemnify the underwriters against certain liabilities and expenses, including liabilities under the Securities Act, in connection with the sales of the shares reserved for the directed share program.

Other relationships

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

An affiliate of Cowen and Company, LLC, which is acting as an underwriter in this offering, purchased 13,559 shares of our Series C convertible preferred stock for $11.06228216 per share, for a total purchase price of $149,999.47. These shares are deemed to be underwriting compensation under FINRA Rule 5110. The Series C convertible preferred stock will automatically convert into an aggregate of 13,559 shares of our common stock in connection with this offering. In connection with the purchase of our Series C convertible preferred stock, we and the holders of our Series C convertible preferred stock entered into the Rights Agreement, which grants to holders of our outstanding convertible preferred stock certain rights, including certain registration rights, and also contains a market stand-off provision imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus. See the sections titled “Description of Capital Stock — Registration Rights” and “Shares eligible for future sale — Lock-up arrangements” for additional information.

Selling restrictions

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed

by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in the European Economic Area and the United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom (each a "Relevant State"), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and us that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, us or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in Australia

This document:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the "Corporations Act");
- has not been, and will not be, lodged with the Australian Securities and Investments Commission ("ASIC"), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act ("Exempt Investors").

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those shares to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any "resident" of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (the "SFO") of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong) (the "CO") or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made thereunder.

Notice to Prospective Investors in Singapore

Singapore SFA Product Classification—In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of shares, we have has determined, and hereby notify all relevant persons (as defined in Section 309A(1) of the SFA), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Each representative has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each representative has represented and agreed that it has not offered or sold any shares or caused the shares to be made the subject of an invitation for subscription or purchase and will not offer or sell any shares or cause the shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, whether directly or indirectly, to any person in Singapore other than:

(a) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the "SFA")) pursuant to Section 274 of the SFA;

(b) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA; or

(c) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(i) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(ii) where no consideration is or will be given for the transfer;

(iii) where the transfer is by operation of law;

(iv) as specified in Section 276(7) of the SFA; or

(v) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Notice to Prospective Investors in China

This prospectus will not be circulated or distributed in the PRC and the shares will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

Notice to Prospective Investors in Korea

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder (the "FSCMA"), and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder (the "FETL"). The shares have not been listed on any of securities exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

Notice to Prospective Investors in Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the shares has been or will be registered with the Securities Commission of Malaysia ("Commission") for the Commission's approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services Licence; (iii) a person who acquires the shares, as principal, if the offer is on terms that the shares may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the shares is made by a holder of a Capital Markets Services Licence who

carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

Notice to Prospective Investors in Taiwan

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

Notice to Prospective Investors in Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority ("CMA") pursuant to resolution number 2-11-2004 dated October 4, 2004 as amended by resolution number 1-28-2008, as amended (the "CMA Regulations"). The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

Notice to Prospective Investors in Qatar

The shares described in this prospectus have not been, and will not be, offered, sold or delivered, at any time, directly or indirectly in the State of Qatar in a manner that would constitute a public offering. This prospectus has not been, and will not be, registered with or approved by the Qatar Financial Markets Authority or Qatar Central Bank and may not be publicly distributed. This prospectus is intended for the original recipient only and must not be provided to any other person. It is not for general circulation in the State of Qatar and may not be reproduced or used for any other purpose.

Notice to Prospective Investors in the Dubai International Financial Centre ("DIFC")

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority ("DFSA"). This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

Notice to Prospective Investors in the United Arab Emirates

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United

Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

Notice to Prospective Investors in Bermuda

Shares may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to Prospective Investors in the British Virgin Islands

The shares are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of the Issuer. The shares may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands),"BVI Companies"), but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

Notice to Prospective Investors in South Africa

Due to restrictions under the securities laws of South Africa, no "offer to the public" (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted) (the "South African Companies Act"))is being made in connection with the issue of the shares in South Africa. Accordingly, this document does not, nor is it intended to, constitute a "registered prospectus" (as that term is defined in the South African Companies Act) prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. The shares are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions stipulated in section 96 (1) applies:

Section 96(1) (a)	the offer, transfer, sale, renunciation or delivery is to: (i) persons whose ordinary business, or part of whose ordinary business, is to deal in securities, as principal or agent; (ii) the South African Public Investment Corporation; (iii) persons or entities regulated by the Reserve Bank of South Africa; (iv) authorised financial service providers under South African law; (v) financial institutions recognised as such under South African law; (vi) a wholly-owned subsidiary of any person or entity contemplated in (c), (d) or (e), acting as agent in the capacity of an authorised portfolio manager for a pension fund, or as manager for a collective investment scheme (in each case duly registered as such under South African law); or (vii) any combination of the person in (i) to (vi); or
Section 96(1) (b)	the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than ZAR1,000,000 or such higher amount as may be promulgated by notice in the Government Gazette of South Africa pursuant to section 96(2)(a) of the South African Companies Act.

Information made available in this prospectus should not be considered as "advice" as defined in the South African Financial Advisory and Intermediary Services Act, 2002.

No South African residents or offshore subsidiary of a South African resident may subscribe for or purchase any of the shares or beneficially own or hold any of the shares unless specific approval has been obtained from the financial surveillance department of the South African Reserve Bank (the "SARB") by such persons or such subscription, purchase or beneficial holding or ownership is otherwise permitted under the South African Exchange Control Regulations or the rulings promulgated thereunder (including, without limitation, the rulings issued by the SARB providing for foreign investment allowances applicable to persons who are residents of South Africa under the applicable exchange control laws of South Africa).

Notice to Prospective Investors in Chile

THESE SECURITIES ARE PRIVATELY OFFERED IN CHILE PURSUANT TO THE PROVISIONS OF LAW 18,045, THE SECURITIES MARKET LAW OF CHILE, AND NORMA DE CARÁCTER GENERAL NO. 336 ("RULE 336"), DATED JUNE 27, 2012, ISSUED BY THE SUPERINTENDENCIA DE VALORES Y SEGUROS DE CHILE ("SVS"), THE SECURITIES REGULATOR OF CHILE, TO RESIDENT QUALIFIED INVESTORS THAT ARE LISTED IN RULE 336 AND FURTHER DEFINED IN RULE 216 OF JUNE 12, 2008 ISSUED BY THE SVS.

PURSUANT TO RULE 336 THE FOLLOWING INFORMATION IS PROVIDED IN CHILE TO PROSPECTIVE RESIDENT INVESTORS IN THE OFFERED SECURITIES:

1. THE INITIATION OF THE OFFER IN CHILE IS NOVEMBER 16, 2020.

2. THE OFFER IS SUBJECT TO NCG 336 OF JUNE 27, 2012 ISSUED BY THE SUPERINTENDENCIA DE VALORES Y SEGUROS DE CHILE (SUPERINTENDENCY OF SECURITIES AND INSURANCE OF CHILE).

3. THE OFFER REFERS TO SECURITIES THAT ARE NOT REGISTERED IN THE REGISTRO DE VALORES (SECURITIES REGISTRY) OR THE REGISTRO DE VALORES EXTRANJEROS (FOREIGN SECURITIES REGISTRY) OF THE SVS AND THEREFORE:

a. THE SECURITIES ARE NOT SUBJECT TO THE OVERSIGHT OF THE SVS; AND

b. THERE ISSUER THEREOF IS NOT SUBJECT TO REPORTING OBLIGATION WITH RESPECT TO ITSELF OR THE OFFERED SECURITIES.

4. THE SECURITIES MAY NOT BE PUBLICLY OFFERED IN CHILE UNLESS AND UNTIL THEY ARE REGISTERED IN THE SECURITIES REGISTRY OF THE SVS.

INFORMACIÓN A LOS INVERSIONISTAS RESIDENTES EN CHILE

LOS VALORES OBJETO DE ESTA OFERTA SE OFRECEN PRIVADAMENTE EN CHILE DE CONFORMIDAD CON LAS DISPOSICIONES DE LA LEY N° 18.045 DE MERCADO DE VALORES, Y LA NORMA DE CARÁCTER GENERAL N° 336 DE 27 DE JUNIO DE 2012 ("NCG 336") EMITIDA POR LA SUPERINTENDENCIA DE VALORES Y SEGUROS DE CHILE, A LOS "INVERSIONISTAS CALIFICADOS" QUE ENUMERA LA NCG 336 Y QUE SE DEFINEN EN LA NORMA DE CARÁCTER GENERAL N° 216 DE 12 DE JUNIO DE 2008 EMITIDA POR LA MISMA SUPERINTENDENCIA.

EN CUMPLIMIENTO DE LA NCG 336, LA SIGUIENTE INFORMACIÓN SE PROPORCIONA A LOS POTENCIALES INVERSIONISTAS RESIDENTES EN CHILE:

1. LA OFERTA DE ESTOS VALORES EN CHILE COMIENZA EL DÍA 16 DE NOVIEMBRE DE 2020.

2. LA OFERTA SE ENCUENTRA ACOGIDA A LA NCG 336 DE FECHA ECHA 27 DE JUNIO DE 2012 EMITIDA POR LA SUPERINTENDENCIA DE VALORES Y SEGUROS.

3. LA OFERTA VERSA SOBRE VALORES QUE NO SE ENCUENTRAN INSCRITOS EN EL REGISTRO DE VALORES NI EN EL REGISTRO DE VALORES EXTRANJEROS QUE LLEVA LA SUPERINTENDENCIA DE VALORES Y SEGUROS, POR LO QUE:

a) LOS VALORES NO ESTÁN SUJETOS A LA FISCALIZACIÓN DE ESA SUPERINTENDENCIA; Y

b) EL EMISOR DE LOS VALORES NO ESTÁ SUJETO A LA OBLIGACIÓN DE ENTREGAR INFORMACIÓN PÚBLICA SOBRE LOS VALORES OFRECIDOS NI SU EMISOR.

4. LOS VALORES PRIVADAMENTE OFRECIDOS NO PODRÁN SER OBJETO DE OFERTA PÚBLICA EN CHILE MIENTRAS NO SEAN INSCRITOS EN EL REGISTRO DE VALORES CORRESPONDIENTE.

Notice to Prospective Investors in Brazil

For purposes of Brazilian law, this offer of securities is addressed to you personally, upon your request and for your sole benefit, and is not to be transmitted to anyone else, to be relied upon elsewhere or for any other purpose either quoted or referred to in any other public or private document or to be filed with anyone, without our prior express and written consent.

This offering does not constitute or form part of any public offering of shares in Brazil and, accordingly, has not been and will not be registered under Brazilian Federal Law No. 6385 of December 7, 1976, as amended, Brazilian Securities Commission (CVM) Rule (Instrução) No. 400 of December 29, 2003, as amended, or under any other Brazilian securities law or regulation. Furthermore, our shares and we have not been and will not be registered before the CVM under CVM Rule (Instrução) No. 480 of December 7, 2009, as amended.

Therefore, the shares offered hereby have not been, will not be and may not be offered for sale or sold in Brazil except in circumstances that do not constitute a public offering or other unauthorized distribution under applicable Brazilian laws and regulations. Documents relating to the shares, as well as the information contained therein, may not be supplied to the public as a public offering in Brazil or be used in connection with any offer for subscription or sale of the shares to the public in Brazil.

Notice to Prospective Investors in the Cayman Islands

No invitation, whether directly or indirectly, may be made to the public in the Cayman Islands to subscribe for our securities.

Notice to Prospective Investors in Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares of common stock is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and “qualified individuals,” each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Notice to Prospective Investors in Kuwait

Unless all necessary approvals from the Kuwait Capital Markets Authority pursuant to Law No. 7/2010, its Executive Regulations, and the various Resolutions and Announcements issued pursuant thereto or in connection therewith have been given in relation to the marketing of and sale of the shares, these may not be offered for sale, nor sold in the State of Kuwait (“Kuwait”). Neither this prospectus nor any of the information contained herein is intended to lead to the conclusion of any contract of whatsoever nature within Kuwait. With regard to the contents of this document we recommend that you consult a licensee as per the law and specialized in giving advice about the purchase of shares and other securities before making the subscription decision.

Legal matters

The validity of the shares of our common stock being offered in this prospectus will be passed upon for us by Cooley LLP, San Francisco, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Davis Polk & Wardwell LLP, Menlo Park, California.

Experts

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2019 and 2018, and for each of the two years in the period ended December 31, 2019, as set forth in their report. We've included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

Where you can find additional information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC also maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

On the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above.

We also maintain a website at www.olema.com. Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference.

Olema Pharmaceuticals, Inc.
Index to financial statements

Report of independent registered public accounting firm

To the Stockholders and the Board of Directors of
Olema Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Olema Pharmaceuticals, Inc. (the Company) as of December 31, 2018 and 2019, and the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, 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 at December 31, 2018 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on 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.

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2020.

Redwood City, California
September 18, 2020,
except for the effects of the reverse stock split discussed in Note 14, as to which the date is November 16, 2020

Olema Pharmaceuticals, Inc.
Balance Sheets
(Amounts in thousands, except share and per share amounts)

	December 31,		September 30, 2020	Pro Forma Stockholders' Equity as of September 30, 2020
	2018	2019	(unaudited)	(unaudited)
Assets				
Current assets:				
Cash and cash equivalents	$3,149	$ 68	$ 127,824	$
Prepaid expenses and other current assets	93	35	1,263	
Total current assets	3,242	103	129,087	
Property and equipment, net	26	26	24	
Deferred offering costs	—	—	1,476	
Other assets	3	3	96	
Total assets	$3,271	$ 132	$ 130,683	$
Liabilities, convertible preferred stock and stockholders' equity (deficit)				
Current liabilities:				
Accounts payable	$ 116	$ 935	$ 97	$
Other current liabilities	85	443	5,176	
Total current liabilities	201	1,378	5,273	
Total liabilities	201	1,378	5,273	
Commitments and Contingencies (Note 12)				
Convertible preferred stock (Series A, A-1, B, and C), $0.0001 par value; 12,903,514, 12,903,514 and 66,897,006 shares authorized as of December 31, 2018 and 2019 and September 30, 2020 (unaudited), respectively; 4,628,215, 4,628,215 and 23,765,075 shares issued and outstanding as of December 31, 2018 and 2019 and September 30, 2020 (unaudited), respectively; aggregate liquidation preference of $9,432, $9,432 and $150,350 as of December 31, 2018 and 2019 and September 30, 2020 (unaudited), respectively; no shares issued or outstanding, pro forma as of September 30, 2020 (unaudited)	9,348	9,348	148,373	—
Stockholders' equity (deficit):				

	December 31,		September 30,	Pro Forma Stockholders' Equity as of September 30,
	2018	2019	2020	2020
			(unaudited)	(unaudited)
Common stock, $0.0001 par value; 22,000,000, 22,000,000 and 88,000,000 shares authorized as of December 31, 2018 and 2019 and September 30, 2020 (unaudited), respectively; 2,804,937, 2,804,937 and 3,754,663 shares issued as of December 31, 2018 and 2019 and September 30, 2020 (unaudited), respectively ; 2,593,316, 2,593,316 and 2,859,272 shares outstanding as of December 31, 2018 and 2019 and September 30, 2020 (unaudited), respectively; 27,519,738 shares issued and 26,624,347 shares outstanding, pro forma as of September 30, 2020 (unaudited)	—	—	—	3
Additional paid-in capital	168	168	—	148,370
Accumulated deficit	(6,446)	(10,762)	(22,963)	(22,963)
Total stockholders' equity (deficit)	(6,278)	(10,594)	(22,963)	125,410
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 3,271	$ 132	$ 130,683	$ 130,683

See accompanying notes to the financial statements.

Olema Pharmaceuticals, Inc.
Statements of operations and comprehensive loss
(Amounts in thousands, except share and per share amounts)

	Years Ended December 31,		Nine Months Ended September 30,	
	2018	2019	2019	2020
			(unaudited)	
Operating expenses:				
Research and development	$ 1,693	$ 3,920	$ 3,010	$ 7,415
General and administrative	386	403	296	3,982
Total operating expenses	2,079	4,323	3,306	11,397
Loss from operations	(2,079)	(4,323)	(3,306)	(11,397)
Other (expense) income:				
Interest income	4	7	7	59
Interest expense	(28)	—	—	(653)
Other income	—	—	—	1
Loss on extinguishment of convertible notes	(63)	—	—	—
Loss on remeasurement of convertible notes	(31)	—	—	—
Total other (expense) income, net	(118)	7	7	(593)
Net loss and comprehensive loss	$ (2,197)	$ (4,316)	(3,299)	(11,990)
Repurchase and retirement of Series A and Series A-1 convertible preferred stock	—	—	—	(1,869)
Net loss attributable to common stockholders	$ (2,197)	$ (4,316)	$ (3,299)	$ (13,859)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.87)	$ (1.66)	$ (1.27)	$ (5.29)
Weighted average shares used to compute net loss per share attributable to common stockholders, basic and diluted	2,522,577	2,593,316	2,593,316	2,617,543
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		$ (0.60)		$ (0.98)
Weighted average shares used to compute pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		7,221,531		14,098,571

See accompanying notes to the financial statements.

Olema Pharmaceuticals, Inc.
Statements of convertible preferred stock and stockholders' deficit
(Amounts in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balances at December 31, 2017	1,664,309	$ 3,377	2,464,217	$ —	$ 73	$ (4,249)	$ (4,176)
Issuance of Series A-1 convertible preferred stock, net of issuance costs of $68	2,447,657	4,931	—	—	—	—	—
Issuance of Series A-1 convertible preferred stock in connection with convertible notes, net of issuance costs of $15	516,249	1,040	—	—	—	—	—
Issuance of common stock upon conversion of convertible notes, net of issuance costs of $1	—	—	129,099	—	94	—	94
Stock-based compensation expense	—	—	—	—	1	—	1
Net loss and comprehensive loss	—	—	—	—	—	(2,197)	(2,197)
Balances at December 31, 2018	4,628,215	9,348	2,593,316	—	168	(6,446)	(6,278)
Net loss and comprehensive loss	—	—	—	—	—	(4,316)	(4,316)
Balances at December 31, 2019	4,628,215	9,348	2,593,316	—	168	(10,762)	(10,594)
Beneficial conversion option recognized upon issuance of 2020 convertible notes	—	—	—	—	1,054	—	1,054
Beneficial conversion option recognized upon repurchase of 2020 convertible notes on settlement date	—	—	—	—	(2,568)	—	(2,568)
Extinguishment of 2020 convertible notes	—	—	—	—	2,148	—	2,148
Issuance of Series B convertible preferred stock, net of issuance costs of $256	10,801,277	50,637	—	—	—	—	—
Issuance of Series B convertible preferred stock in connection with the conversion of convertible notes	638,270	3,007	—	—	—	—	—
Repurchase and retirement of Series A and Series A-1 convertible preferred stock	(206,821)	(420)	—	—	(1,658)	(211)	(1,869)
Issuance of Series C convertible preferred stock, net of issuance costs of $1,637	7,904,135	85,801	—	—	—	—	—
Exercise of stock options	—	—	239,055	—	120	—	120
Vesting of restricted stock awards	—	—	26,901	—	—		
Stock-based compensation expense	—	—	—	—	736	—	736
Net loss and comprehensive loss	—	—	—	—	—	(11,990)	(11,990)
Balances at September 30, 2020 (unaudited)	23,765,075	$ 148,373	2,859,272	$ —	$ —	$ (22,963)	$ (22,963)
Balances at December 31, 2018	4,628,215	$ 9,348	2,593,316	$ —	$ 168	$ (6,446)	$ (6,278)
Net loss and comprehensive loss	—	—	—	—	—	(3,299)	(3,299)
Balances at September 30, 2019 (unaudited)	4,628,215	$ 9,348	2,593,316	$ —	$ 168	$ (9,745)	$ (9,577)

See accompanying notes to the financial statements.

Olema Pharmaceuticals, Inc.
Statements of cash flows
(Amounts in thousands)

	Year Ended December 31,		Nine Months Ended September 30,	
	2018	2019	2019	2020
			(unaudited)	
Cash flows from operating activities:				
Net loss	$ (2,197)	$ (4,316)	$ (3,299)	$ (11,990)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization expense	8	9	6	7
Non-cash interest expense	28	—	—	641
Stock-based compensation expense	1	—	—	736
Loss on extinguishment of convertible notes	63	—	—	—
Loss on remeasurement of convertible notes	31	—	—	—
Changes in operating assets and liabilities:				
Prepaid expenses, other current assets and other assets	(78)	58	15	(1,321)
Accounts payable and other current liabilities	(32)	1,168	1,045	1,074
Net cash used in operating activities	(2,176)	(3,081)	(2,233)	(10,853)
Cash flows from investing activities:				
Purchase of equipment	—	—	—	(5)
Net cash used in investing activities	—	—	—	(5)
Cash flows from financing activities:				
Proceeds from the issuance of convertible notes	323	—	—	3,000
Proceeds from issuance of Series A-1 convertible preferred stock, net of issuance costs	4,931	—	—	—
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs	—	—	—	50,637
Proceeds from issuance of Series C convertible preferred stock, net of issuance costs	—	—	—	87,427
Repurchase of shares of Series A and Series A-1 convertible preferred stock	—	—	—	(2,289)
Exercise of stock options	—	—	—	640
Proceeds from the settlement of non-recourse notes	—	—	—	88
Payments of costs related to initial public offering	—	—	—	(889)
Net cash provided by financing activities	5,254	—	—	138,614
Net increase (decrease) in cash and cash equivalents	3,078	(3,081)	(2,233)	127,756
Cash and cash equivalents at beginning of period	71	3,149	3,149	68
Cash and cash equivalents at end of period	$ 3,149	$ 68	$ 916	$ 127,824
Supplemental disclosure of non-cash investing and financing activities:				
Conversion of convertible notes and accrued interest into Series A-1 convertible preferred stock	$ 1,040	$ —	$ —	$ —
Purchases of property and equipment included in accounts payable	$ —	$ 9	$ —	$ —
Conversion of convertible notes into Series B convertible preferred stock	$ —	$ —	$ —	$ 3,007
Deferred offering costs included in other current liabilities	$ —	$ —	$ —	$ 587
Series C convertible preferred stock issuance costs included in other current liabilities	$ —	$ —	$ —	$ 1,626

See accompanying notes to the financial statements.

Olema Pharmaceuticals, Inc.
Notes to financial statements

1. Nature of the Business and Basis of Presentation

Olema Pharmaceuticals Inc. (“Olema” or the “Company”) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of next generation targeted therapies for women’s cancers. The Company is initially focused on developing therapies for the treatment of breast cancer. The Company’s wholly owned, lead product candidate, OP-1250, is a novel oral therapy with combined activity as both a complete ER antagonist and a selective ER degrader. The Company is currently evaluating OP-1250 in a Phase 1/2 dose escalation and expansion trial for the treatment of recurrent, locally advanced or metastatic estrogen receptor-positive human epidermal growth factor receptor 2-negative breast cancer.

The Company is located in San Francisco, California and was incorporated in Delaware on August 7, 2006 under the legal name of CombiThera, Inc. and on March 25, 2009 was renamed to Olema Pharmaceuticals, Inc. All of the Company’s tangible assets are held in the United States (“U.S.”).

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, successful discovery and development of its product candidates, development by competitors of new technological innovations, dependence on key personnel, the ability to attract and retain qualified employees, protection of proprietary technology, compliance with governmental regulations, the impact of the COVID-19 coronavirus, the ability to secure additional capital to fund operations and commercial success of its product candidates. OP-1250 and any future product candidates the Company may develop will require extensive nonclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure and extensive compliance-reporting capabilities. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Need for Additional Capital

Since inception, the Company has incurred net losses and negative cash flows from operations, including net losses of $2.2 million and $4.3 million during the years ended December 31, 2018 and 2019, respectively, and $3.3 million and $12.0 million for the nine months ended September 30, 2019 and 2020 (unaudited), respectively. As of December 31, 2019 and September 30, 2020 (unaudited), the Company had an accumulated deficit of $10.8 million and $23.0 million, respectively, and expects to incur substantial operating losses and negative cash flows from operations for the foreseeable future. The Company had $0.1 million and $127.8 million of cash and cash equivalents at December 31, 2019 and September 30, 2020 (unaudited), respectively. During the nine months ended September 30, 2020 (unaudited) the Company raised $50.9 million and $87.4 million of gross proceeds in connection with the issuance of its Series B convertible preferred stock and Series C convertible preferred stock (see Note 7, "Convertible Preferred Stock"), respectively, which management believes is sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance operations. The Company is seeking to complete an initial public offering (“IPO”) of its common stock. In the event the Company does not complete an IPO, the Company expects to seek additional funding through private equity financings, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may not be able to obtain financing on acceptable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company’s stockholders.

If the Company is unable to obtain funding, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance

that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Impact of the COVID-19 Coronavirus

The COVID-19 pandemic continues to rapidly evolve. The extent of the impact of the COVID-19 pandemic on the Company's business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on the Company's development activities, planned clinical trial enrollment, future trial sites, CROs, third-party manufacturers, and other third parties with whom the Company does business, as well as its impact on regulatory authorities and the Company's key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, the Company is conducting business as usual, with necessary or advisable modifications to employee travel and with the Company's employees working remotely. The Company will continue to actively monitor the rapidly evolving situation related to the COVID-19 pandemic and may take further actions that alter the Company's operations, including those that may be required by federal, state or local authorities, or that the Company determines are in the best interests of its employees and other third parties with whom the Company does business. At this point, the extent to which the COVID-19 pandemic may affect the Company's business, operations and development timelines and plans, including the resulting impact on expenditures and capital needs, remains uncertain.

Basis of Presentation

The financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying balance sheet as of September 30, 2020, the statements of operations and comprehensive loss and of cash flows for the nine months ended September 30, 2019 and 2020, and the statement of convertible preferred stock and stockholders' equity (deficit) for the nine months ended September 30, 2020 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2020 and the results of its operations and its cash flows for the nine months ended September 30, 2019 and 2020. The financial data and other information disclosed in these notes related to the nine months ended September 30, 2019 and 2020 are unaudited. The results for the nine months ended September 30, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020, any other interim periods, or any future year or period.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Such estimates include the determination of useful lives for equipment, accruals of research and development expenses, accrual of research contract costs, preferred and common stock and stock option valuations. On an ongoing basis, the Company evaluates its estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Unaudited Pro Forma Information

Upon the completion of an IPO, all outstanding shares of convertible preferred stock will automatically convert into shares of common stock. Unaudited pro forma balance sheet information as of September 30, 2020 assumes the conversion of all outstanding shares of convertible preferred stock into 23,765,075 shares of common stock. The shares of common stock issuable and any proceeds expected to be received in an IPO are excluded from such pro forma financial information. The unaudited pro forma basic and diluted net loss per common share has been computed to give effect to the conversion of all outstanding shares of convertible preferred stock into shares of common stock as if the proposed IPO had occurred on the later of January 1, 2019 or the issuance date of the convertible preferred stock. The unaudited pro forma net loss per common share does not include the common shares expected to be sold and related proceeds to be received from an IPO.

Cash and Cash Equivalents

Cash and cash equivalents are defined as short-term, highly liquid investments with original maturities of 90 days or less at the date of purchase. Cash deposits are all in reputable financial institutions in the U.S. and as of December 31, 2018 and 2019 and September 30, 2020 (unaudited), cash and cash equivalents consisted of cash on deposit with U.S. banks denominated in U.S. dollars and investments in interest bearing money market funds.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. The Company invests its excess cash with large financial institutions. At times, the Company's cash balances with individual banking institutions will exceed the limits insured by the FDIC, however, the Company has not experienced any losses on such deposits.

The Company's future results of operations involve a number of other risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's current and potential future product candidates, uncertainty of market acceptance of the Company's product candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals or sole-source suppliers.

The Company's product candidates require approvals from the U.S. Food and Drug Administration and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed or the Company was unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction to the carrying value of additional paid-in capital generated as a result of such offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations and comprehensive loss. As of December 31, 2018 and 2019, the Company did not have any deferred offering costs. As of September 30, 2020 (unaudited), the Company had recorded $1.5 million of deferred offering costs related to its planned IPO.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The three levels of inputs that may be used to measure fair value are defined below:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.

- Level 2 — Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, such as quoted prices for similar assets or liabilities, quoted prices 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 assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of the Company's other assets, accounts payable and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred to discover, research and develop product candidates, including personnel expenses, stock-based compensation expense, allocated facility-related and depreciation expenses, third-party license fees and external costs including fees paid to consultants and clinical research organizations ("CROs"), in connection with nonclinical studies and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered.

Costs incurred in obtaining technology licenses are charged immediately to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future uses.

Research Contract Costs and Accruals

The Company has from time to time entered into various research and development and other agreements with commercial firms, researchers, universities and others for provisions of goods and services. These agreements are generally cancelable, and the related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives. The general range of useful lives of equipment are as follows:

	Estimated Useful Life
Lab equipment	5 – 7 years
Computer equipment	5 years

When assets are sold or retired, the cost and related accumulated depreciation are removed from the accounts, with any resulting gain or loss recorded in operating expenses in the statements of operations and comprehensive loss. Costs of repairs and maintenance are expensed as incurred.

Impairment of Long-Lived Assets

The Company's long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset or asset group may not be recoverable. Recoverability of an asset to be held and used is measured by a comparison of the carrying amount of an asset or asset group to the future undiscounted cash flows expected to be generated by the asset or asset group. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. As of December 31, 2018 and 2019 and September 30, 2020 (unaudited), the Company has not recorded any impairment losses on its long-lived assets.

Income Taxes

Income taxes are computed using the asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's financial statements. In estimating future tax consequences, the Company considers all expected future events other than enactment of changes in tax laws or rates. A valuation allowance is recorded, if necessary, to reduce net deferred tax assets to their realizable values if management does not believe it is more likely than not that the net deferred tax assets will be realized. As of December 31, 2018 and 2019 and September 30, 2020 (unaudited), the Company has recorded a full valuation allowance against its net deferred tax assets.

The Company follows the provisions of the authoritative guidance from the Financial Accounting Standards Board, ("FASB"), on accounting for uncertainty in income taxes. These provisions provide a comprehensive model for the recognition, measurement and disclosure in financial statements of uncertain income tax positions that a company has taken or expects to take on a tax return. Under these provisions, a company can recognize the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit can be recognized. Assessing an uncertain tax position begins with the initial determination of the sustainability of the position and is measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed. Additionally, the Company must accrue interest and related penalties, if applicable, on all tax exposures for which reserves have been established consistent with jurisdictional tax laws.

The Company has analyzed its filing positions in all significant Federal and state jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. The Company had no unrecognized tax benefits for the years ended December 31, 2018 and 2019 and the nine months ended September 30, 2020 (unaudited), respectively. With few exceptions, the Company is no longer subject to U.S. Federal, state, and local tax examinations by tax authorities for years before 2016, although carry-forward attributes that were generated prior to 2019 may still be adjusted upon examination by the taxing authorities if they either have been or will be used in a future period (see Note 10, "Income Taxes").

The Company's policy is to recognize interest and penalties related to uncertain tax positions in the provision for income taxes. As of December 31, 2018 and 2019 and September 30, 2020 (unaudited), the Company had no accrued interest or penalties related to uncertain tax positions

Common Stock Valuation

Due to the absence of an active market for the Company's common stock, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. In determining the fair value of options granted, the Company has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including:

- the prices at which the Company sold shares of convertible preferred stock and the superior rights and preferences of the convertible preferred stock relative to its common stock at the time of each grant;
- the progress of the Company's research and development programs, including the status and results of nonclinical studies for its product candidates;
- the Company's stage of development and commercialization and its business strategy;
- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- the Company's financial position, including cash on hand, and its historical and forecasted performance and operating results;
- the lack of an active public market for the Company's common stock and convertible preferred stock;
- the likelihood of achieving a liquidity event, such as an IPO or sale of the Company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biotechnology industry.

Significant changes to the key assumptions underlying the factors used could have resulted in different fair values of common stock at each valuation date.

Comprehensive Loss

There was no difference between net loss and comprehensive loss for each of the periods presented in the accompanying financial statements.

Stock-Based Compensation

All stock-based compensation cost, including grants of stock options and restricted stock awards issued under the Company's equity incentive plan, is measured at the grant date based on the fair value of the award and is recognized as an expense on a straight-line basis over the requisite service period, which is generally the vesting period. The Company recognizes stock compensation in accordance with ASC 718, Compensation — Stock Compensation ("ASC 718"). ASC 718 requires the recognition of compensation expense, using a fair-value-based method, for costs related to all share-based payments including stock options. ASC 718 requires companies to estimate the fair value of share-based payment awards on the date of grant. The Company's determination of the fair value of stock options with time-based vesting on the date of grant utilizes the Black-Scholes option-pricing model. The Company estimates the expected option lives using historical data, volatility using stock prices of peer companies, risk-free rates using the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term equal to the expected term, and dividend yield using the Company's expectations and historical data. The Company uses the simplified method to calculate the expected term of employee stock option grants. Under the simplified method, the expected term is estimated to be the mid-point between the vesting date and the contractual term of the option. For awards with graded vesting, in which specified tranches of the options vest on different dates, the Company uses a single weighted average expected life to value the entire award, which is

equal to the average of the weighted average vesting period of the award and the contractual term of the award. The fair value of each stock option grant is calculated based upon the Company's common stock valuation on the date of the grant. Equity instruments issued to nonemployees are recorded at their fair value on the grant date and without subsequent remeasurement. The amount of stock-based compensation expense recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest, including awards with graded vesting. As part of the requirements of ASC 718, the Company has elected to account for forfeitures of stock option grants as they occur.

Net Loss Per Common Share

The Company follows the two-class method when computing net income (loss) per common share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per common share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net income (loss) per common share is computed by dividing the net income (loss) per common share by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per common share is computed by adjusting net income (loss) to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per common share is computed by dividing the diluted net loss by the weighted average number of common shares outstanding for the period, including potential dilutive common shares. For purpose of this calculation, outstanding stock options and convertible preferred stock are considered potential dilutive common shares.

The Company's convertible preferred stock contractually entitles the holders of such shares to participate in dividends but do not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such securities. In periods in which the Company reported a net loss, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss for the years ended December 31, 2018 and 2019 and the nine months ended September 30, 2019 and 2020 (unaudited).

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB under its ASC or other standard setting bodies.

The Company is an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). Under the JOBS Act, companies have extended transition periods available for complying with new or revised accounting standards. The Company has elected to use this exemption to delay adopting new or revised accounting standards until such time as those standards apply to private companies. Where allowable, the Company has early adopted certain standards as described below.

Recently Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2019-12, "Income Taxes (ASC 740): Simplifying the Accounting for Income Taxes," which simplifies the accounting for income taxes by removing certain exceptions to the general principles in ASC 740 and clarifies and amends existing guidance to improve consistent application. The standard will be effective for the Company beginning in the first quarter of fiscal year beginning after December 15, 2021, with early adoption permitted. The amendments that are related to changes in ownership of foreign equity method investments or foreign subsidiaries are to be applied on a modified retrospective basis through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. The amendments that are related to franchise

taxes that are partially based on income are to be applied on either a retrospective basis for all periods presented or a modified retrospective basis through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. All other amendments under this ASU are to be applied on a prospective basis. The Company has early adopted the guidance effective January 1, 2020. The adoption of this new standard did not have a material impact on our financial statements.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement, which modifies the disclosure requirements for fair value measurements. The Company adopted this standard on January 1, 2020. The adoption of ASU 2018-13 had no impact on the Company's financial statements.

In June 2018, the FASB issued ASU 2018-07, Improvements to Nonemployee Share-Based Payment Accounting (Topic 718), which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company adopted this standard on January 1, 2018. The adoption of this standard did not have a material impact on the Company's financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation — Stock Compensation: Improvements to Employee Share-Based Payment Accounting, (Topic 718). The new guidance simplifies certain aspects related to income taxes, statements of cash flows, and forfeitures when accounting for share-based payment transactions. Certain of the amendments related to timing of the recognition of tax benefits and tax withholding requirements should be applied using a modified retrospective transition method. Amendments related to the presentation of the statements of cash flows should be applied retrospectively. All other provisions may be applied on a prospective or modified retrospective basis. The Company adopted this standard on January 1, 2018. The adoption of this standard did not have a material impact on the Company's financial statements.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606) which amended the existing FASB Accounting Standards Codification. ASU 2014-09 supersedes the revenue recognition requirements in Revenue Recognition (Topic 605) and establishes a principle for recognizing revenue upon the transfer of promised goods or services to customers, in an amount that reflects the expected consideration received in exchange for those goods or services. The standard also provides guidance on the recognition of costs related to obtaining and fulfilling customer contracts. Additionally, the standard requires disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

ASU 2014-09, as amended, is effective for fiscal 2019, including interim periods within that reporting period. The standard allows for two different methods of adoption. The full retrospective method allows the amendment to be applied retrospectively to each prior period presented, and the modified retrospective method allows the amendment to be applied with the cumulative effect recognized as of the date of initial application. The Company early adopted this standard on January 1, 2018 and the adoption had no impact on the Company's financial position, results of operations or cash flows as the Company does not currently have any revenue-generating arrangements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. For non-public entities, ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2021, including interim periods within those fiscal years, and early adoption is permitted. The Company is in the process

of completing its review of its existing lease agreements under Topic 842 and does not expect the adoption of ASU 2016-02 to have a material impact on its financial position, results of operations or cash flows.

In August 2020, the FASB issued ASU 2020-06, Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40). The new standard reduces the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models results in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Convertible instruments that continue to be subject to separation models are (1) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (2) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. The standard also amends the guidance for the derivatives scope exception for contracts in an entity's own equity. For non-public entities, ASU 2020-06 is effective for annual reporting periods beginning after December 15, 2023, including interim periods within those fiscal years, and early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company is in the process of completing its review of its existing convertible instruments under Topic 470 and 815 and does not expect the adoption of ASU 2020-06 to have a material impact on its financial position, results of operations, or cash flows.

3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,		September 30,
	2018	2019	2020
			(unaudited)
Prepaid clinical trial costs	$ —	$ —	$ 935
Other	93	35	328
	$ 93	$ 35	$ 1,263

4. Property and Equipment, net

Property and equipment, net consisted of the following (in thousands):

	December 31,		September 30,
	2018	2019	2020
			(unaudited)
Lab equipment	$ 80	$ 89	$ 88
Computer equipment	17	17	23
Property and equipment, gross	97	106	111
Less: Accumulated depreciation	(71)	(80)	(87)
Property and equipment, net	$ 26	$ 26	$ 24

The Company recognized depreciation expense related to these assets of $8,244 and $9,033 during the years ended December 31, 2018 and 2019, respectively, and $6,615 and $7,080 during the nine months ended September 30, 2019 and 2020 (unaudited), respectively.

5. Other Current Liabilities

Other current liabilities consisted of the following (in thousands):

	December 31,		September 30,
	2018	2019	2020
			(unaudited)
Accrued professional fees	$ —	$ —	$ 2,919
Accrued employee bonuses	—	—	495
Accrued R&D related costs	—	—	915
Early exercise of unvested options	—	—	608
Other	85	443	239
	$ 85	$ 443	$ 5,176

6. Convertible Notes

2017 Convertible Notes

In 2017, the Company issued convertible promissory notes (the “2017 Notes”) in the aggregate principal amount of approximately $0.7 million. The 2017 Notes bore interest at a rate of 6.0% per annum, were unsecured, and were due and payable, including accrued interest, on the first to occur of December 31, 2017 and receipt by the Company of an aggregate amount of cash from any sources equal to or greater than $2.0 million. In the event of a qualified sale of equity securities resulting in gross proceeds to the Company of at least $2.0 million (including conversion of the 2017 Notes), the noteholders had an option to convert the 2017 Notes for a number of shares of the Company’s convertible preferred stock issued in such a financing equal to the outstanding balance plus accrued interest divided by the price paid by investors in the financing plus a number of shares of common stock equal to 25% of the number of shares of convertible preferred stock issuable as a result of the qualified sale. In the event of a change of control, the 2017 Notes contained a put option whereby the Company was required to pay the holder of the 2017 Notes an amount equal to 150% of the balance immediately prior to such change of control unless the holders of the 2017 Notes elected to convert such notes into a number of shares equal to the balance divided by a conversion price equal to $5.0 million divided by the number of shares of common stock outstanding immediately prior to the closing of the change of control. In addition, in the event a qualified sale of preferred stock had not occurred and the 2017 Notes had not been converted, the 2017 Notes could have been converted at a price equal to $5.0 million divided by the number of shares of common stock outstanding immediately prior to the conversion upon maturity, at the noteholder’s option. On December 31, 2017, the 2017 Notes became immediately due and payable. However, the Notes were not settled and continued to accrue interest until their extinguishment on July 19, 2018. The Company recorded total interest expense related to the 2017 Notes of $48,838 through the date of extinguishment.

On July 19, 2018, the Company issued Series A-1 convertible preferred stock. In connection with this offering, holders of the 2017 Notes and the Company agreed to extinguish the unpaid principal and accrued interest due on the 2017 Notes for 341,936 shares of A-1 convertible preferred stock and 85,510 shares of common stock. The Company recorded an extinguishment loss of $0.1 million related to the 2017 Notes, reflecting the difference between the fair value of the A-1 convertible preferred stock and common stock received and the carrying amounts of the 2017 Notes including accrued interest.

2018 Convertible Notes

In 2018, the Company issued convertible promissory notes (the “2018 Notes”) in the aggregate of approximately $0.4 million. The 2018 Notes bore interest at a rate of 6.0% per annum, were unsecured, and were due and payable, including accrued interest, on June 30, 2019. In the event of a qualified sale of equity securities resulting in gross proceeds to the Company of at least $3.0 million (including conversion of the 2017 Notes and the

2018 Notes), all principal and accrued and unpaid interest under the 2018 Notes would be automatically converted into a number of shares of the company's convertible preferred stock equal to the balance divided by the price per share paid by investors in the financing plus the number of shares of common stock equal to 25% of the number of shares of convertible preferred stock issued as a result of the qualified sale. In the event of a change of control, the 2018 Notes contained a put option whereby the Company was required to pay the holders of the 2018 Notes an amount equal to 150% of the balance immediately prior to such change of control or the amount the holder would have received if immediately prior to the change of control, the balance had converted into common stock at a conversion price equal to $5.0 million divided by the number of shares of common stock outstanding immediately prior to the change of control. In addition, in the event of a qualified sale of preferred stock had not occurred and the 2018 Notes had remained outstanding, the 2018 Notes would have automatically been converted into common stock at a price equal to $5.0 million divided by the number of shares of common stock outstanding immediately prior to the conversion upon maturity. The Company elected the fair value option for the 2018 Notes. Subsequent changes in fair value, including the impact of any coupon interest payable, being recognized through the statements of operations and comprehensive loss as other income (expense) until the 2018 Notes are settled. The fair value of the 2018 Notes liability included all payable amounts; therefore a separate payable was not recorded for accrued interest. All issuance costs associated with the 2018 Notes were expensed at the issuance date.

On July 19, 2018, the Company completed a qualified financing, and issued to holders of the 2018 Notes 174,313 shares of Series A-1 convertible preferred stock, and 43,589 shares of common stock (see Note 5, "Convertible Preferred Stock" and Note 6 "Common Stock"). Immediately prior to settlement, the 2018 Notes were remeasured to their final fair value, which equaled the fair value of the equity consideration to be received upon settlement (i.e., the shares of convertible preferred stock, and common stock). The Company recorded a loss on remeasurement of $31,483 and $6,090 of interest expense with respect to the 2018 Notes during the year ended December 31, 2018.

In connection with the issuance of the 2018 Notes, the Company paid an immaterial amount of legal costs, which were expensed.

2020 Convertible Notes

On January 3, 2020 ("issuance date"), the Company issued convertible promissory notes (the "2020 Notes") in the aggregate principal amount of $3.0 million. The 2020 Notes bore interest at a rate of 1.21% per annum, were unsecured and were due and payable, including accrued interest, on May 2, 2020 ("maturity date"). The Company was not permitted to prepay the outstanding principal and interest without the consent of the note holders. In the event of a default, all unpaid principal and accrued interest would become immediately due.

In the event of a qualified sale of preferred stock prior to the maturity date ("qualified financing") with gross proceeds to the Company of at least $13.0 million (inclusive of the conversion of the 2020 notes), the outstanding principal and interest outstanding under the 2020 Notes would automatically convert into preferred stock at a conversion price equal to the price paid per share by the investors in the qualified financing.

In the event of a non-qualified sale of preferred stock prior to the maturity date, note holders would have had the option to convert the outstanding principal and interest under the 2020 Notes into the securities sold as part of the non-qualified financing at a conversion price equal to the price paid per share by the investors in the non-qualified financing.

If within five business days prior to the maturity date, the Company had not consummated a qualified financing, holders would have had the option to convert the outstanding principal and interest into Series A-1 preferred stock at a conversion price equal to the original price paid per share for the Series A-1 financing ($2.043).

In the event the Company was sold prior to repayment or conversion of the 2020 notes, the note holders would have had the option (i) for the Company to pay an amount equal to two times the aggregate outstanding balance of principal and with interest accruing at a rate of 8% per annum, or (ii) to convert the aggregate outstanding

principal and accrued interest into Series A-1 Preferred Stock at a price equal to the lowest price at which the Company has sold shares of Series A-1 Preferred Stock ($2.043).

On the issuance date the Company determined that the conversion option associated with the 2020 Notes met the definition of a beneficial conversion feature ("BCF") as the fair value of the underlying instrument at the time of issuance exceeded the contractual conversion price. The BCF was recognized at its aggregate intrinsic value of $1.1 million as a debt discount with a corresponding credit to additional paid-in capital in the Company's balance sheet. The debt discount was amortized over the term of the 2020 Notes through the recognition of interest expense via the effective interest method.

On March 17, 2020 (the "settlement date"), the Company issued and sold 2,545,277 shares of Series B convertible preferred stock at $4.712 per share for gross proceeds of approximately $12.0 million (see Note 7, "Convertible Preferred Stock"). On the settlement date, the principal and accrued interest then outstanding under the 2020 Notes of $3.0 million were converted into 638,270 shares of Series B convertible preferred stock ("March 2020 conversion").

On the settlement date, the unamortized debt discount on the 2020 Notes was $0.4 million and the intrinsic value of the BCF was $2.6 million representing an increase of $1.5 million from the issuance date of the 2020 Notes. The March 2020 conversion was accounted for as a debt extinguishment. However, as the note holders were previous investors of the Company, the increase in the intrinsic value of the BCF was deemed to be a capital contribution and therefore not income attributable to common stockholders, and accordingly, the Company recorded the $1.5 million gain on extinguishment of the debt within additional paid-in capital.

7. Convertible Preferred Stock

As of December 31, 2018 and 2019, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 4,640,126 shares of Series A convertible preferred stock at par value of $0.0001 per share. On June 30, 2014, the Company issued 1,664,309 shares of Series A convertible preferred stock at $2.030 per share for consideration of $3.4 million. In September 2020, the Company purchased and retired 181,503 shares of Series A convertible preferred stock from investors at a price of $11.063 per share, or approximately $2.0 million.

On July 19, 2018, and as amended on August 1, 2018, the Company authorized the sale and issuance of up to 8,263,388 shares of Series A-1 convertible preferred stock at par value of $0.0001. On July 19, 2018, the Company issued 2,447,657 shares of Series A-1 convertible preferred stock at $2.043 per share for gross proceeds of $5.0 million, and issued 516,249 shares of Series A-1 convertible preferred stock with a fair value of $1.1 million in connection with the conversion of the 2017 Notes and 2018 Notes (see Note 6, "Convertible Notes"). In September 2020, the Company purchased and retired 25,318 shares of Series A-1 convertible preferred stock at a price of $11.063 per share or approximately $0.3 million.

Series B Convertible Preferred Stock

On March 13, 2020, the Company filed its fourth amended and restated certificate of incorporation, which authorized the Company to sell and issue up to 26,627,219 shares of Series B convertible preferred stock with a par value of $0.0001 per share. On March 17, 2020, the Company issued and sold 2,545,277 shares of Series B convertible preferred stock at $4.712 per share for gross proceeds of approximately $12.0 million. At the same time, the Company issued an additional 638,270 shares of Series B convertible preferred stock in conjunction with its conversion of the 2020 Notes (see Note 6, "Convertible Notes," "2020 Convertible Notes"), for a total of 3,183,547 shares of Series B convertible preferred stock issued on March 17, 2020. On March 20, 2020, the Company issued and sold 3,183,550 shares of Series B convertible preferred stock at $4.712 per share for gross proceeds of approximately $15.0 million. On May 28, 2020, the Company filed an amendment to its fourth amended and restated certificate of incorporation, which authorized the Company to sell and issue up to 32,781,066 shares of Series B convertible preferred stock. On June 1, 2020, the Company issued and sold 5,072,450 shares of Series B convertible preferred stock at $4.712 per share for gross proceeds of

approximately $23.9 million (collectively, “Series B convertible preferred stock issuances”). In total, 11,439,547 shares of Series B convertible preferred stock were issued for gross cash proceeds of approximately $50.9 million.

The Company incurred issuance costs in connection with the sale and issuance of the Series B convertible preferred stock of $0.3 million.

On September 3, 2020, the Company filed a second amendment to its fourth amended and restated certificate of incorporation. The amendment had the impact of reducing the authorized number of shares of Series B convertible preferred stock to 31,893,492, the number of shares then outstanding.

Series C Convertible Preferred Stock (unaudited)

On September 29, 2020, the Company filed its fifth amended and restated certificate of incorporation, which authorized the sale of 22,100,000 shares of Series C convertible preferred stock. On September 30, 2020, the Company issued and sold 7,904,135 shares of Series C convertible preferred stock at $11.063 per share for gross proceeds of approximately $87.4 million. The Company incurred issuance costs in connection with the sale and issuance of the Series C convertible preferred stock of $1.6 million.

The Series A convertible preferred stock, Series A-1 convertible preferred stock, Series B convertible preferred stock and Series C convertible preferred stock are collectively referred to as “ convertible preferred stock.” As of each balance sheet date, convertible preferred stock consisted of the following (in thousands, except share amounts):

	As of December 31, 2018 and 2019				
	Convertible preferred stock Authorized	Convertible preferred stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A convertible preferred stock	4,640,126	1,664,309	$ 3,377	$ 3,377	1,664,309
Series A-1 convertible preferred stock	8,263,388	2,963,906	5,971	6,055	2,963,906
	12,903,514	4,628,215	$ 9,348	$ 9,432	4,628,215

	As of September 30, 2020 (unaudited)				
	Convertible Preferred Stock Authorized	Convertible Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A convertible preferred stock	4,640,126	1,482,866	$ 3,009	$ 3,009	1,482,866
Series A-1 convertible preferred stock	8,263,388	2,938,587	5,919	6,003	2,938,587
Series B convertible preferred stock	31,893,492	11,439,547	53,644	53,900	11,439,547
Series C convertible preferred stock	22,100,000	7,904,135	85,801	87,438	7,904,135
	66,897,006	23,765,075	$148,373	$ 150,350	23,765,075

The rights and privileges of the holders of the convertible preferred stock are as follows:

Conversion

Each share of convertible preferred stock is convertible on a one-to-one basis, subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization at the option of the stockholder and subject to adjustments in accordance with anti-dilution provisions. In addition, the convertible preferred stock automatically converts into shares of common stock at the closing of (i) a qualified IPO pursuant to

an effective registration statement filed under the Securities Act of 1933 that results in gross proceeds to the Company of not less than $50.0 million or (ii) the date specified by vote or written consent of the holders of a majority of the outstanding shares of convertible preferred stock, voting together as a single class on an as converted basis. The number of common stock shares to be issued upon conversion is determined by dividing the original issue price for the relevant series of convertible preferred stock by the conversion price for such series. The conversion price for the convertible preferred stock is initially the original issue price of the convertible preferred stock, or $2.030 per share for Series A convertible preferred stock, $2.043 per share of Series A-1 convertible preferred stock, $4.712 per share of Series B convertible preferred stock and $11.063 per share of Series C convertible preferred stock, each subject to adjustment.

Liquidation Preference

In the event of any liquidation, dissolution, or winding up of the Company, either voluntarily or involuntarily, the holders of outstanding convertible preferred stock shall be entitled to receive, on a pari passu basis, prior and in preference to any distribution of any of the assets of this Company to the holders of Common Stock, an amount per share equal to the Series A convertible preferred stock original issue price of $2.030 per share, the Series A-1 convertible preferred stock original issue price of $2.043 per share, the Series B convertible preferred stock original issue price of $4.712 per share and the Series C convertible preferred stock original issue price of $11.063 per share, respectively, plus any dividends declared but unpaid (as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations or the like with respect to the convertible preferred stock). If, upon the occurrence of such event, the assets distributed among the holders of convertible preferred stock shall be insufficient then the entire assets of the Company legally available for distribution shall be distributed ratably among the holders of the convertible preferred stock in proportion to the respective amounts which would otherwise be payable if all amounts payable related to the shares were paid in full.

Dividends

All dividends are declared pro rata on the common stock and the convertible preferred stock on a pari passu basis according to the number of shares of common stock held by such owners. For this purpose each convertible preferred stock stockholder is treated as holding the greatest whole number of shares of common stock then issuable upon conversion of all shares of held convertible preferred stock. Through December 31, 2019 and September 30, 2020 (unaudited), no cash dividends have been declared or paid by the Company.

Voting Rights

The holders of convertible preferred stock are entitled to a number of votes equal to the number of whole shares of common stock into which each share of convertible preferred stock is convertible as of the record date for determining stockholders entitled to vote on such matter. With respect to such vote, such holder the same voting rights of the holders of common stock. Except as require d by law or by the provisions of the Company's amended and restated certificate of incorporation, holders of convertible preferred stock and common stock vote together as one class on an as-converted basis.

Holders of shares of Series B convertible preferred stock, voting as a separate class on an as converted basis, are entitled to elect two directors of the Company. The holders of shares of Series C convertible preferred stock, voting as a separate class on an as converted basis, are entitled to elect one director of the Company. Holders of common stock, voting together as a separate class, are entitled to elect two directors of the company. The holders of the outstanding shares of common stock and convertible preferred stock, voting as a single class on an as-converted basis, are entitled to elect the remaining authorized directors.

Redemption

The holders of convertible preferred stock have certain liquidation rights in the event of a deemed liquidation that, in certain situations, is not solely within the control of the Company and would call for the redemption of the then outstanding convertible preferred stock. Therefore, the convertible preferred stock are classified outside of

shareholders' deficit on the balance sheets. The carrying value of the convertible preferred stock is not subsequently remeasured to the redemption value until the contingent redemption events are considered to be probable of occurring.

8. Common Stock

As of December 31, 2018 and 2019, the Company's amended and restated certificate of incorporation, authorized the Company to issue 22,000,000 shares of common stock with a par value of $0.0001 per share. On March 13, 2020, the Company filed its fourth amended and restated certificate of incorporation which authorized the Company to issue 53,500,000 shares of common stock with a par value of $0.0001. On May 28, 2020, the Company filed a certificate of amendment to increase the number of authorized shares of common stock to 59,653,847 at a par value of $0.0001. On September 3, 2020, the Company filed a second amendment to its fourth amended and restated certificate of incorporation, increasing the number of authorized shares to 65,000,000 shares of common stock with a par value of $0.0001. On September 29, 2020, the Company filed a fifth amended and restated certificate of incorporation which authorized the Company to issue 88,000,000 shares of common stock with a par value of $0.0001 per share.

The voting, dividend and liquidation rights of the holders of the Company's common shares are subject to and qualified by the rights, powers and preferences of the holders of the convertible preferred stock set forth above.

On July 19, 2018, as a result of the conversion of the Notes, the Company issued 129,099 shares of common stock (see Note 6, "Convertible Notes").

As of December 31, 2018 and 2019, there were 22,000,000 shares of common stock authorized, 2,804,940 shares issued and 2,593,316 shares outstanding. As of September 30, 2020 (unaudited), there were 88,000,000 shares of common stock authorized, 3,754,663 shares of common stock issued and 2,859,272 shares of common stock outstanding.

As of each balance sheet date, the Company had reserved shares of common stock for issuance in connection with the following:

	December 31,		September 30,
	2018	2019	2020
			(unaudited)
Conversion of outstanding shares of convertible preferred stock	4,628,215	4,628,215	23,765,075
Options outstanding under the 2014 Stock Plan[(1)(2)]	111,190	111,190	2,639,009
Shares available for future grant under the 2014 Stock Plan	394,548	394,548	1,175,022
Unvested restricted stock awards outstanding under the 2014 Stock Plan	—	—	762,195
	5,133,953	5,133,953	28,341,301

(1) Balance as of December 31, 2018 and 2019 excludes 211,621 shares that were exercised under the non-recourse receivable (see Notes Receivable below).

(2) Balance as of September 30, 2020 (unaudited) includes 133,196 unvested early exercised stock options (see Note 9, "Stock-Based Compensation").

Each common share entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. The holders of shares of common stock, voting as a separate class, are entitled to elect two directors. Common stockholders are entitled to receive dividends, if any, as may be declared by the Company's Board of Directors, subject to the preferential dividend rights of the convertible preferred stock. Through December 31, 2019 and September 30, 2020 (unaudited), no cash dividends had been declared or paid by the Company.

Notes Receivable

In December 2015, the Company entered into two non-recourse notes receivable agreements with certain employees of the Company for $0.1 million and $14,000 (the "Non-Recourse Notes"), respectively, related to the exercise of stock options. The Non-Recourse Notes cover the exercise of 175,753 and 35,868 shares of common stock, accrue simple interest at an annual rate of 1.48%, and mature on February 28, 2025. The Non-Recourse Notes are collateralized by the shares of the Company's common stock issued. Since the Non-Recourse Notes are considered in-substance nonrecourse, the Company has not considered this to be a substantive exercise for accounting purposes and has not recorded the shares outstanding or the Non-Recourse Notes as an asset on the accompanying balance sheets as of December 31, 2018 and 2019. See Note 9, "Stock-Based Compensation" and Note 13, "Related Parties." During September 2020, all outstanding principal and accrued interest relating to the Non-Recourse Notes were settled in full by the two noteholders. As a result, the Company issued 211,621 shares of common stock to the noteholders.

9. Stock-Based Compensation

In 2014, the Company's Board of Directors and stockholders approved and adopted the 2014 Stock Plan (the "Plan"). The Plan is intended to advance the interests of the Company and its stockholders by providing an incentive to attract, retain and reward persons performing services for the Company and by motivating such persons to contribute to the growth and profitability of the Company. The Plan permits the grant of options and restricted stock awards (including restricted stock purchase rights and restricted stock bonus awards). The maximum aggregate number of shares that may be subject to awards and sold under the Plan as of December 31, 2018 and 2019 was 717,360 shares. In March 2020, the Company's Board of Directors and stockholders increased the number of shares under the Plan to 2,331,420 shares. In September 2020, the Company's Board of Directors and stockholders approved additional increases under the Plan to allow for 4,124,820 shares and subsequently 4,842,180 shares. The shares may be authorized but unissued, or reacquired common stock. The exercise price for each option shall be established in the discretion of the Board; provided, however, that (i) the exercise price per share for an option shall be no less than the fair market value of a share of common stock on the effective date of the grant of the option and (ii) no incentive stock option granted to a ten percent stockholder shall have an exercise price per share less than 110% of the fair market value of a share of common stock on the effective date of the grant of the option. Specific vesting for stock options is service related and determined in each award agreement, where stock options are fully vested at the grant date or follow a graded vesting schedule. Options granted under the Plan generally expire ten years after the date of grant. During the nine months ended September 30, 2020, the Company granted to certain directors, employees, and consultants options to purchase 2,555,253 shares of common stock at exercise prices ranging from $2.064 per share to $4.824 per share.

At December 31, 2018 and 2019, 394,548 shares were available for future grants. At September 30, 2020 (unaudited), 1,175,022 shares were available for future grants.

Stock Option Valuation

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors were as follows, presented as a weighted average:

	Years Ended December 31,		Nine Months Ended September 30,	
	2018	2019	2019	2020
			(unaudited)	
Weighted average risk-free interest rate	*	*	*	0.39%
Expected term (in years)	*	*	*	5.90
Expected volatility	*	*	*	77.50%
Expected dividend yield	*	*	*	0%

* There were no stock options granted during the period.

Stock Option Activity

The following table summarizes the stock option activity under the Plan:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2018[1]	322,811	$ 0.39	7.04	$ —
Granted	—	—		
Exercised	—	—		
Forfeited	—	—		
Outstanding as of December 31, 2019[1]	322,811	$ 0.39	6.04	$ —
Granted	2,555,253	4.31		
Exercised	(239,055)	0.48		
Forfeited	—	—		
Outstanding as of September 30, 2020 (unaudited)[2]	2,639,009	$ 4.18	9.75	$ 5,564
Options vested and exercisable as of December 31, 2019	319,075	$ 0.39	6.02	$ —
Options vested and exercisable as of September 30, 2020 (unaudited)	362,272	$ 2.65	8.71	$ 1,314
Options expected to vest as of December 31, 2019	3,736	$ 0.39	7.59	$ —
Options expected to vest as of September 30, 2020 (unaudited)	2,276,737	$ 4.41	9.92	$ 4,250

(1) Inclusive of 211,621 shares that were exercised under a non-recourse note receivable that were legally issued, but not deemed outstanding for accounting purposes (see Note 13, “Related Parties”).

(2) Balance as of September 30, 2020 (unaudited) includes 133,196 unvested early exercised stock options (see Note 8, “Common Stock” and Note 13, “Related Parties”).

The total fair value of options vested during each of the years ended December 31, 2018 and 2019, was $1,000. The total fair value of options vested during the nine months ended September 30, 2020 (unaudited) was $0.6 million.

Early Exercise of Stock Options

In September 2020, one employee and one non-employee paid $0.6 million to early exercise 135,525 options with exercise prices ranging from $4.406 per share to $4.824 per share. As of September 30, 2020, 2,329 shares had vested with the remaining shares vesting over their respective terms. The terms of the Plan permit certain option holders to exercise options before their options are vested, subject to certain limitations. The early exercised options are subject to the same vesting provisions in the original stock option awards. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser's employment, at the price paid by the purchaser. Such shares are not deemed to be outstanding for accounting purposes until they vest and are therefore excluded from shares outstanding and from basic and diluted net loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. A liability is recognized related to the cash proceeds of the unvested options and is reclassified into common stock and additional paid-in capital as the shares vest and the repurchase right lapses. Accordingly, the Company has recorded the unvested portion of the exercise proceeds of $0.6 million in other current liabilities as of September 30, 2020 (unaudited).

Restricted Stock Awards

In June 2020, the Company granted to certain employees 789,096 shares of restricted common stock under the Plan as consideration for services with a deemed value of $2.40 per share, or $1.9 million. The following table summarizes the restricted stock activity under the Plan during the nine months ended September 30, 2020 (unaudited):

	Number of Shares	Grant Date Fair Value
Unvested restricted stock as of December 31, 2019	—	$ —
Granted	789,096	2.40
Vested	(26,901)	2.40
Forfeited	—	—
Unvested restricted stock as of September 30, 2020 (unaudited)	762,195	$ 2.40

Stock-Based Compensation Expense

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company lacks company-specific historical and implied volatility information. Therefore, it estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to nonemployees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Stock-based compensation expense was classified in the statements of operations and comprehensive loss as follows (in thousands):

	Years Ended December 31,		Nine Months Ended September 30,	
	2018	2019	2019	2020
			(unaudited)	
Research and development expenses	$ 1	$ —	$ —	$ 495
General and administrative	—	—	—	241
	$ 1	$ —	$ —	$ 736

10. Income Taxes

The reconciliation of the Federal statutory income tax provision to the Company's effective income tax provision is as follows (in thousands):

	Years Ended December 31,	
	2018	2019
Federal statutory income tax	$ 461	$ 906
State income taxes, net of federal tax benefit	144	300
Other permanent items	(28)	(3)
Valuation allowance	(577)	(1,203)
Provision for income taxes	$ —	$ —

The Company did not record a federal or state income tax provision or benefit for the three months or nine months ended September 30, 2019 and 2020 (unaudited) due to the expected loss before income taxes to be incurred

for the years ended December 31, 2019 and 2020, as well as the Company's continued maintenance of a full valuation allowance against its net deferred tax assets.

Deferred income taxes reflect the net tax effects of loss and credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company's deferred income tax assets and liabilities at December 31, 2018 and 2019 were comprised of the following (in thousands):

	As of December 31,	
	2018	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 1,504	$ 2,706
Equity compensation	6	6
Total deferred tax assets	$ 1,510	$ 2,712
Deferred tax liabilities:		
Fixed assets	$ (5)	$ (4)
Total deferred tax liabilities	$ (5)	$ (4)
Valuation allowance	$(1,505)	$(2,708)
Net deferred tax assets	$ —	$ —

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Based on the level of historical operating results and the uncertainty of the economic conditions, the Company has recorded a valuation allowance of $1.5 million and $2.7 million at December 31, 2018 and 2019, respectively. The change in the valuation allowance for the year end December 31, 2019 was an increase of $1.2 million.

At December 31, 2018 and 2019, the Company had Federal net operating losses (NOLs) of approximately $5.4 million and $9.7 million, and state NOLs of $5.4 million and $9.7 million, respectively. As a result of the Tax Act, for U.S. income tax purposes, NOLs generated in tax years beginning before January 1, 2018 can still be carried forward for up to 20 years, but net operating losses generated for tax years beginning after December 31, 2017 carryforward indefinitely and can be used to offset taxable income. Of the total Federal net operating loss of $9.7 million, $3.3 million will begin to expire in 2032 and $6.3 million will not expire. The state NOL carryover of $9.7 million will begin to expire in 2032.

Pursuant of Internal Revenue Code (IRC) Sections 382 and 383, annual use of the Company's net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes within the meaning of IRC Section 382 are identified as having occurred, the amount of remaining tax attribute carryforwards available to offset future taxable income and income tax expense in future years may be significantly restricted or eliminated. Further, the Company's deferred tax assets associated with such tax attributes could be significantly reduced upon realization of an ownership change within the meaning of IRC Section 382 that has occurred or may occur in the future. Any adjustment to the Company's tax attributes as a result of an ownership change will result in a corresponding decrease to the valuation allowance recorded against the Company's deferred tax assets.

The Company's valuation allowance increased during the years ended December 31, 2019 and 2018 due primarily to the generation of net operating losses, as follows (in thousands):

	Years Ended December 31,	
	2018	2019
Valuation allowance at beginning of year	$ 928	$1,505
Increase recorded to provision for income taxes	577	1,203
Valuation allowance at end of year	$1,505	$2,708

The Company has not incurred any material interest or penalties as of the current reporting date with respect to income tax matters. The Company does not expect that there will be unrecognized tax benefits of a significant nature that will increase or decrease within 12 months of the reporting date. The Company is subject to U.S. Federal income tax as well as income tax in California. The Federal returns for tax years 2017 through 2019 remain open to examination; the state returns remain subject to examination for tax years 2016 through 2019. Carryforward attributes that were generated in years where the statute of limitations is closed may still be adjusted upon examination by the Internal Revenue Service or other respective tax authority.

The Company's policy is to recognize interest expense and penalties related to income tax matters as tax expense. At December 31, 2019, there are no significant accruals for interest related to unrecognized tax benefits or tax penalties.

The unrecognized tax benefit amounts are not reflected in the determination of the Company's deferred tax assets. If recognized, none of these amounts would affect the Company's effective tax rate, since it would be offset by an equal corresponding adjustment in the deferred tax asset valuation allowance. The Company does not foresee material changes to its liability for uncertain tax benefits within the next twelve months.

11. Net Loss Per Common Share and Unaudited Pro Forma Net Loss Per Common Share

Net Loss Per Common Share

Basic and diluted net loss per common share was calculated as follows (in thousands, except share and per share amounts):

	Years Ended December 31,		Nine Months Ended September 30,	
	2018	2019	2019	2020
			(unaudited)	
Numerator:				
Net loss	$ (2,197)	$ (4,316)	$ (3,299)	$ (11,990)
Repurchase and retirement of Series A and Series A-1 convertible preferred stock	—	—	—	(1,869)
Net loss attributable to common stockholders	$ (2,197)	$ (4,316)	$ (3,299)	$ (13,859)
Denominator:				
Weighted average shares used to compute net loss per share attributable to common stockholders, basic and diluted	2,522,577	2,593,316	2,593,316	2,617,543
Net loss per share attributable to common stockholders, basic and diluted	$ (0.87)	$ (1.66)	$ (1.27)	$ (5.29)

The Company's potentially dilutive securities, which include unvested restricted common stock, stock options and convertible preferred stock, have been excluded from the computation of diluted net loss per common share as

the effect would be to reduce the net loss per common share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per common share is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per common share for the periods indicated because including them would have had an anti-dilutive effect:

	Years Ended December 31,		Nine Months Ended September 30,	
	2018	2019	2019	2020
			(unaudited)	
Unvested restricted common stock	—	—	—	762,195
Options to purchase common stock	322,811	322,811	322,811	2,639,009
Convertible preferred stock (as converted to common shares)	4,628,215	4,628,215	4,628,215	23,765,075
	4,951,026	4,951,026	4,951,026	27,166,279

Included in the potentially dilutive options to purchase common stock noted above are 211,621 shares issued upon exercise of options under non-recourse notes receivable during 2015 (see Note 6, “Common Stock,” Note 9, “Stock-Based Compensation” and Note 11, “Related Parties”). The Company determined the purchase of the stock to be non-substantive, and as such, the shares subject to the promissory notes will not be deemed outstanding until such time as the promissory notes have been repaid. Accordingly, the Company has excluded these shares from the calculation of basic and diluted net loss per share for the years ended December 31, 2018 and 2019 and the nine months ended September 30, 2019 (unaudited). During September 2020, all outstanding principal and accrued interest relating to the Non-Recourse Notes were settled in full by the two noteholders, and as a result, the Company issued 211,621 shares of common stock to the noteholders. Also included in the potentially dilutive options to purchase common stock are 133,196 unvested stock options that were early exercised by an employee and a non-employee in September 2020 (unaudited) (see Note 9, “Stock-Based Compensation”). The Company determined the early exercises to be non-substantive as the shares were subject to repurchase rights. Accordingly, the Company has excluded these shares from the calculation of basic and diluted net loss per share for the nine months ended September 30, 2020 (unaudited).

Unaudited Pro Forma Net Loss Per Common Share

The weighted average shares used to compute unaudited pro forma net loss per common share, basic and diluted, for the year ended December 31, 2019 and September 30, 2020 have been prepared to give effect, upon a completion of an IPO, to the automatic conversion of all outstanding shares of convertible preferred stock into shares of common stock as if the proposed IPO had occurred on January 1, 2019.

Unaudited pro forma net loss per common share, basic and diluted, was calculated as follows (in thousands, except share and per share amounts):

	Year Ended December 31, 2019	Nine Months Ended September 30, 2020 (unaudited)
Numerator:		
Net loss attributable to common stockholders	$ (4,316)	$ (13,859)
Denominator:		
Weighted average shares used to compute net loss per share attributable to common stockholders, basic and diluted	2,593,316	2,617,543
Weighted average pro forma adjustment to reflect assumed conversion of convertible preferred stock into common stock upon the closing of a qualified IPO	4,628,215	11,481,028
Weighted average shares used to compute pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)	7,221,531	14,098,571
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)	$ (0.60)	$ (0.98)

12. Commitments and Contingencies

Management Services Agreement

On June 1, 2013, the Company entered into a management services agreement with MandalMed, Inc. (“MandalMed”)(the “MandalMed Services Agreement”). As per the terms of the MandalMed Services Agreement, the Company is permitted to rent approximately 5,762 square feet of MandalMed’s bioscience laboratory, obtain certain administrative and facilities services and use equipment, reagents and supplies from MandalMed. The services agreement commenced on June 1, 2013 and expired September 31, 2013. On June 1, 2013, the Company entered into the first amendment to the MandalMed Services Agreement to add office space, expand the laboratory space and extend the term to September 31, 2013 with the right to extend on a three-month basis. On December 1, 2013, the Company entered into the second amendment to the MandalMed Services Agreement to add office space, lab bench space and extend the term to July 1, 2014 with the right to extend on a six-month basis. On April 15, 2016, the Company entered into the third amendment to the MandalMed Services Agreement to extend the term to June 30, 2016 with six-month extensions. On November 12, 2019, the Company entered into the fourth amendment to the MandalMed Services Agreement to extend the term to June 30, 2018 with six-month extensions. On December 5, 2019, the Company entered into the fifth amendment to the MandalMed Services Agreement to extend the term to June 30, 2020 with automatic six-month extensions unless terminated by either party upon 60 days prior notice. As per the fifth amendment to the MandalMed Services Agreement, the Company is required to maintain a one-time, refundable damage deposit of $3,600 and pay a $6,500 monthly fee for the use of laboratory benches, administrative and facilities services, lab equipment and office space. The Company recorded rent expense of $0.1 million during the years ended December 31, 2018 and 2019, respectively, in connection with the MandalMed Services Agreement. The Company is required to pay future minimum lease payments of $39,000 in 2020 as of December 31, 2019. As neither party opted out of the agreement, it was automatically extended until December 31, 2020. As of September 30, 2020 (unaudited), the Company is required to make future minimum lease payments of $19,500 for the remaining three month term ending December 31, 2020.

On August 27, 2020, the Company entered into a lease agreement with 512 2nd Street LLC to lease approximately 3,500 square feet of office space in San Francisco, California (the “Office Space Lease Agreement”). The Office Space Lease Agreement is for a period of two years commencing on September 1, 2020 and ending August 31, 2022. According to the terms of the Office Space Lease Agreement, the Company paid a $0.1 million security

deposit and is required to pay monthly rent and common area charges. Rent is $23,330 and $24,030 for the first and second years of the lease term, respectively.

The following table summarizes the future minimum lease payments due under operating leases as of September 30, 2020 (unaudited) (in thousands):

Year Ending December 31,	
2020 (remaining)	$2,488
2021	283
2022	192
2023	—
2024	—
Thereafter	—
	$2,963

Clinical Collaboration and Supply Agreement

On July 22, 2020, the Company entered into a non-exclusive clinical collaboration and supply agreement with Novartis Institutes for BioMedical Research, Inc. (“Novartis”) (the “Novartis Agreement”). The collaboration is focused on the evaluation of the safety, tolerability and efficacy of OP-1250 in combination with Novartis’ proprietary CDK4/6 inhibitor Kisqali® (ribociclib) and/or Novartis’ proprietary phosphatidylinositol 3-kinase inhibitor Piqray® (alpelisib) (collectively the “Novartis Study Drugs”) as part of the Company’s planned Phase 1b clinical trial of OP-1250 in patients with metastatic estrogen receptor-positive breast cancer. The Company will be responsible for the conduct of the clinical trials for the combined therapies in accordance with a mutually agreed development plan. As part of the collaboration, the parties granted to each other a non-exclusive, royalty-free license under certain of the parties’ respective background patent rights and other technology to use the parties’ respective study drugs in research and development, solely to the extent reasonably needed for the other party’s activities in the collaboration. All inventions and data developed in the performance of the clinical trials for the combined therapies (other than those specific to each component study drug), will be jointly owned by the parties.

The Company is responsible for manufacturing, packaging and labeling OP-1250, and for packaging and labeling all drugs used in the clinical trials for the combined therapies (other than the Novartis Study Drugs). Novartis is responsible for manufacturing and delivering to the Company the Novartis Study Drugs in such quantities as reasonably needed for the clinical trials for the combined therapies. In accordance with an agreed budget, subject to certain thresholds, Novartis will reimburse the Company for a majority of the direct outside costs that the Company incurs related to conducting the activities under the agreed development plan in conducting the clinical trials for the combined therapies.

The Novartis Agreement will terminate upon completion of all activities outlined in the development plan and the relevant protocols. Either party may terminate the Novartis Agreement for the uncured material breach or insolvency of the other party, if it reasonably deems it necessary in order to protect the safety, health or welfare of subjects enrolled in the clinical trials for the combined therapies due to the existence of a material safety issue, or in certain circumstances for an unresolved clinical hold with respect to either the Novartis Study Drugs or OP-1250. In addition, Novartis may terminate the Novartis Agreement if certain disputes between the parties are not resolved after following the applicable dispute resolution procedures, and the Company may terminate the Novartis Agreement in the event the Company terminates all clinical trials of the combined therapies other than due to a material safety issue or upon a clinical hold.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be

made, and such expenditures can be reasonably estimated. For all periods presented, the Company was not a party to any pending material litigation or other material legal proceedings.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its Board of Directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. As of December 31, 2018 and 2019, the Company had not incurred any material costs as a result of such indemnifications.

13. Related Parties

In December 2015, the Company entered into notes receivable agreements with certain employees of the Company for $0.1 million and $14,000, respectively, related to exercises of stock options. The Non-Recourse Notes cover the exercise of 175,753 and 35,868 shares of common stock, accrue simple interest at an annual rate of 1.48%, and mature on February 28, 2025. The Non-Recourse Notes are collateralized by the shares of the Company's common stock issued. Since the notes are considered in-substance nonrecourse, the Company has not considered this to be a substantive exercise for accounting purposes and has not recorded the shares outstanding or the Non-Recourse Notes as an asset on the accompanying balance sheets. See Note 8, "Common Stock," Note 9, "Stock-Based Compensation" and Note 14, "Subsequent Events."

During September 2020 (unaudited), all outstanding principal and accrued interest relating to the Non-Recourse Notes were settled in full by the two noteholders, and as a result, the Company issued 211,621 shares of common stock to the noteholders.

In September 2020, an employee and a non-employee early exercised 135,525 stock options, 133,196 of which were unvested as of September 30, 2020 (unaudited) (see Note 9, "Stock-Based Compensation").

14. Subsequent Events

For its financial statements as of December 31, 2019 and the year then ended, management has reviewed and evaluated material subsequent events from the balance sheet date of December 31, 2019, through September 18, 2020, which is the date the financial statements were available to be issued.

2020 Convertible Promissory Notes

On January 3, 2020, the Company issued convertible promissory notes (the "2020 Notes") in the aggregate principal amount of $3.0 million. The 2020 Notes bore interest at a rate of 1.21% per annum, were unsecured and were due and payable, including accrued interest, on May 2, 2020. In the event of a qualified sale of equity securities resulting in gross proceeds to the Company of at least $13.0 million, all principal and accrued and unpaid interest under the 2020 Notes would automatically convert into a number of shares of the Company's convertible preferred stock issued in such a financing equal to the balance divided by the price paid by investors in the financing.

Series B Convertible Preferred Stock

On March 13, 2020, the Company's filed its fourth amended and restated certificate of incorporation, which authorized the Company to sell and issue up to 26,627,219 shares of Series B convertible preferred stock with a par value of $0.0001 per share.

On March 17, 2020, the Company issued and sold 2,545,277 shares of Series B convertible preferred stock at $4.712 per share for gross proceeds of approximately $12.0 million. This excludes shares issued upon conversion of the 2020 Notes, which are discussed under “Conversion of the 2020 Notes in Connection with the Series B Preferred Stock Financing” below.

On March 20, 2020, the Company issued and sold 3,183,550 shares of Series B convertible preferred stock at $4.712 per share for approximately $15.0 million.

On May 28, 2020, the Company filed an amendment to its fourth amended and restated certificate of incorporation, which authorized the Company to sell and issue up to 32,781,066 shares of Series B convertible preferred stock.

On June 1, 2020, the Company issued and sold 5,072,450 shares of Series B convertible preferred stock at $4.712 per share for approximately $23.9 million.

The Company incurred issuance costs on the Series B convertible preferred stock issuances on March 17, 2020, March 20, 2020 and June 1, 2020 of $0.3 million.

Conversion of the 2020 Notes in Connection with the Series B Preferred Stock Financing

The Series B convertible preferred stock financing constituted a qualified financing under the 2020 Notes, triggering an automatic conversion of the unpaid principal and accrued interest into 638,270 shares of Series B convertible preferred stock.

Clinical Collaboration and Supply Agreement

On July 22, 2020, the Company entered into a non-exclusive clinical collaboration and supply agreement with Novartis Institutes for BioMedical Research, Inc. (“Novartis”) (the “Novartis Agreement”). The collaboration is focused on the evaluation of the safety, tolerability and efficacy of OP-1250 in combination with Novartis’ proprietary CDK4/6 inhibitor Kisqali® (ribociclib) and/or Novartis’ proprietary phosphatidylinositol 3-kinase inhibitor Piqray® (alpelisib) (collectively the “Novartis Study Drugs”) as part of the Company’s planned Phase 1b clinical trial of OP-1250 in patients with metastatic estrogen receptor-positive breast cancer. The Company will be responsible for the conduct of the clinical trials for the combined therapies in accordance with a mutually agreed development plan. As part of the collaboration, the parties granted to each other a non-exclusive, royalty-free license under certain of the parties’ respective background patent rights and other technology to use the parties’ respective study drugs in research and development, solely to the extent reasonably needed for the other party’s activities in the collaboration. All inventions and data developed in the performance of the clinical trials for the combined therapies (other than those specific to each component study drug), will be jointly owned by the parties.

The Company is responsible for manufacturing, packaging and labeling OP-1250, and for packaging and labeling all drugs used in the clinical trials for the combined therapies (other than the Novartis Study Drugs). Novartis is responsible for manufacturing and delivering to the Company the Novartis Study Drugs in such quantities as reasonably needed for the clinical trials for the combined therapies. In accordance with an agreed budget, subject to certain thresholds,Novartis will reimburse the Company for a majority of the direct outside costs that the Company incurs related to conducting the activities under the agreed development plan in conducting the clinical trials for the combined therapies.

The Novartis Agreement will terminate upon completion of all activities outlined in the development plan and the relevant protocols. Either party may terminate the Novartis Agreement for the uncured material breach or insolvency of the other party, if it reasonably deems it necessary in order to protect the safety, health or welfare of subjects enrolled in the clinical trials for the combined therapies due to the existence of a material safety issue, or in certain circumstances for an unresolved clinical hold with respect to either the Novartis Study Drugs or OP-1250. In addition, Novartis may terminate the Novartis Agreement if certain disputes between the parties are not resolved after following the applicable dispute resolution procedures, and the Company may terminate

the Novartis Agreement in the event the Company terminates all clinical trials of the combined therapies other than due to a material safety issue or upon a clinical hold.

Lease Agreement

On August 27, 2020, the Company entered into a lease agreement with 512 2nd Street LLC to lease approximately 3,500 square feet of office space in San Francisco, California (the "Office Space Lease Agreement"). The Office Space Lease Agreement is for a period of two years commencing on September 1, 2020 and ending August 31, 2022. According to the terms of the Office Space Lease Agreement, the Company paid a $0.1 million security deposit and is required to pay monthly rent of $23,330 and $24,030 for the first and second years of the lease term, respectively.

Amendment of Fourth Amended and Restated Certificate of Incorporation

On September 3, 2020, the Company filed a second amendment to its fourth amended and restated certificate of incorporation. Following such amendment, the authorized capital stock of the Company was as follows: 109,797,006 shares, of which 65,000,000 shares are common stock and 44,797,006 shares are convertible preferred stock, 4,640,126 of which are designated Series A convertible preferred stock, 8,263,388 of which are designated Series A-1 convertible preferred stock, and 31,893,492 of which are designated Series B convertible preferred stock.

Amendments to 2014 Stock Plan

In March 2020, the Company's Board of Directors and stockholders approved an increase in the number of shares reserved for issuance under the Plan from 717,360 shares to 2,331,420 shares.

In September 2020, the Company's Board of Directors and stockholders approved an increase in the number of shares reserved for issuance under the Plan from 2,331,420 shares to 4,124,820 shares.

Restricted Stock Awards

In June 2020, as described below, the Company granted to certain employees 789,096 shares of restricted common stock under the Plan. These non-cash issuances were as consideration for services at an estimated fair value of $2.40, for aggregate consideration of $1.9 million.

Executive Officers

In May 2020, the Company entered into an employment agreement with Kinney Horn to serve as the Company's Chief Business Officer, reporting directly to the CEO. Mr. Horn is entitled to an initial base salary, effective May 25, 2020, of $375,000 per year, and a year-end incentive bonus, beginning in 2020, targeted at 35% of Mr. Horn's base salary, as determined by the Company's Board of Directors. In addition, Mr. Horn was granted an option to purchase an aggregate of 252,060 shares of common stock with an exercise price of $2.064 per share.

In June 2020, the Company entered into an employment agreement with Shane Kovacs to serve as the Company's Chief Financial Officer and Chief Operating Officer, reporting directly to the CEO. Mr. Kovacs is entitled to an initial base salary, effective June 15, 2020, of $400,000 per year, and a year-end incentive bonus, beginning in 2020, targeted at 35% of his base salary, as determined by the Company's Board of Directors. In addition, Mr. Kovacs was granted a restricted stock award of 358,680 shares of common stock.

In June 2020, the Company entered into an offer letter that governs the current terms of Cyrus L. Harmon, Ph.D.'s employment. Pursuant to the agreement, Dr. Harmon is entitled to an initial annual base salary, effective January 1, 2020, of $450,000, and is eligible to receive an annual performance bonus with a target achievement of 45% of his base salary, as determined by the Company's Board of Directors. In addition, Mr. Harmon was granted a restricted stock award of 143,472 shares of common stock. In September 2020, in connection with his transition to the role of Chief Technology Officer, Dr. Harmon's annual base salary increased to $500,000, and he was granted an option to purchase 227,859 shares of common stock with an exercise price of $4.824 per share.

In June 2020, the Company entered into an offer letter that governs the current terms of Peter Kushner, Ph.D.'s employment. Pursuant to the agreement, Dr. Kushner will continue to serve as the Company's Chief Scientific Officer and is entitled to an initial annual base salary, effective January 1, 2020, of $350,000, is eligible to receive an annual performance bonus with a target achievement of 30% of his base salary, as determined by the Company's Board of Directors. In addition, Dr. Kushner was granted a restricted stock award of 143,472 shares of common stock.

In June 2020, the Company entered into an offer letter that governs the current terms of David Myles, Ph.D.'s employment. Pursuant to the agreement, Dr. Myles will serve as the Company's Chief Development Officer and is entitled to an initial annual base salary, effective January 1, 2020, of $340,000, is eligible to receive an annual performance bonus with a target achievement of 30% of his base salary, as determined by the Company's Board of Directors. In addition, Dr. Myles was granted a restricted stock award of 143,472 shares of common stock.

In September 2020, the Company entered into an employment agreement with Sean Bohen, M.D., Ph.D., to serve as the Company's Chief Executive Officer. Dr. Bohen is entitled to an initial base salary, effective September 1, 2020, of $0.5 million per year, and a performance bonus equal to 50% of his annual base salary (prorated for 2020), as determined by the Company's Board of Directors. In addition, Dr. Bohen was granted an option to purchase 1,110,896 shares of common stock with an exercise price of $4.824 per share.

In September 2020, the Company entered into an employment agreement with John Moriarty, J.D. to serve as the Company's Executive Vice President, Chief Legal Officer and Corporate Secretary. Mr. Moriarty is entitled to an initial base salary, effective September 8, 2020, of $0.4 million per year, and a performance bonus equal to 35% of his annual base salary (prorated for 2020), as determined by the Company's Board of Directors. In addition, Mr. Moriarty was granted the option to purchase 252,060 shares of common stock with an exercise price of $4.824 per share.

Stock Option Grants

Subsequent to December 31, 2019, the Company granted to certain directors, employees, and consultants options to purchase 2,555,253 shares of common stock (including the option grants described above) at exercise prices ranging from $2.064 per share to $4.824 per share.

During September 2020, in connection with the Non-Recourse Notes, all outstanding principal and accrued interest relating to the Non-Recourse Notes were fully repaid by the two noteholders, and as a result, the Company issued 175,753 and 35,868 shares of common stock to the noteholders, respectively.

Reverse Stock Split

On November 13, 2020, the Company filed an amended and restated certificate of incorporation to effect a 1-for-2.788 reverse split of shares of the Company's issued and outstanding common stock and convertible preferred stock (the "Reverse Stock Split"). The par value of the common stock and preferred stock was not adjusted as a result of the Reverse Stock Split. The Company did not adjust the number of authorized shares of common stock or convertible preferred stock. All references to common stock and convertible preferred stock, options to purchase common stock, early exercised options, restricted stock awards, share data, per share data and related information contained in these financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

15. Subsequent Events (Unaudited)

For the interim financial statements as of September 30, 2020 (unaudited), and for the nine months then ended, the Company evaluated subsequent events through October 23, 2020, the date on which those financial statements were issued.

11,000,000 shares

Common stock

Prospectus

J.P. Morgan **Jefferies** **Cowen**
Canaccord Genuity

November 18, 2020