

## PROSPECTUS

5,400,000 Shares

**aura**

Common Stock

This is the initial public offering of shares of our common stock. We are offering 5,400,000 shares of our common stock. 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 Market under the symbol "AURA." The initial public offering price of our common stock is \$14.00 per share.

We are an "emerging growth company" and a "smaller reporting company" under applicable Securities and Exchange Commission rules and will be subject to reduced public company reporting requirements for this prospectus and future filings.

**Our business and investment in our common stock involves significant risks. These risks are described under the caption "[Risk Factors](#)" beginning on page 12 of this prospectus.**

Neither the Securities and Exchange Commission nor any state securities commission approved or disapproved of the securities that may be offered under this prospectus, nor have any of these organizations determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	<u>Per Share</u>	<u>Total</u>
Initial public offering price	\$ 14.00	\$75,600,000
Underwriting discounts and commissions(1)	\$ 0.98	\$ 5,292,000
Proceeds, before expenses, to Aura Biosciences, Inc.	\$ 13.02	\$70,308,000

(1) See the section titled "Underwriting" for additional information regarding compensation payable to the underwriters. We have agreed to reimburse the underwriters for certain expenses in connection with the offering.

We have granted the underwriters an option for a period of 30 days to purchase up to 810,000 additional shares of our common stock from us at the public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the shares of common stock against payment on November 2, 2021.

*Joint Book-Running Managers***Cowen****SVB Leerink****Evercore ISI**

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*Lead Manager***BTIG**

October 28, 2021

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representation other than those contained in this prospectus, any amendment or supplement to this prospectus or 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. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus, any amendment or supplement to this prospectus or 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 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 in the United States. Persons outside 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 the United States.

The market data and certain other statistical information used throughout this prospectus are based on independent industry publications, governmental publications, reports by market research firms, or other independent sources that we believe to be reliable sources. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this prospectus, and we

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believe that these sources are reliable; however, we have not independently verified the information contained in such publications. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section entitled "Risk Factors" and elsewhere in this prospectus. Some data are also based on our good faith estimates.

## PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes included elsewhere in this prospectus. You should also consider, among other things, the matters described under “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” in each case appearing elsewhere in this prospectus. Unless the context otherwise requires, the terms “Aura,” “Aura Biosciences,” “the Company,” “the Registrant,” “we,” “us,” and “our” in this prospectus refer to Aura Biosciences, Inc.

### Overview

We are a clinical-stage biotechnology company leveraging our novel targeted oncology platform to develop a potential new standard of care across multiple cancer indications, with an initial focus on ocular and urologic oncology. Our proprietary platform enables the targeting of a broad range of solid tumors using Virus-Like Particles, or VLPs, that can be conjugated with drugs or loaded with nucleic acids to create Virus-Like Drug Conjugates, or VDCs. Our VDCs are largely agnostic to tumor type and can recognize a surface marker, known as heparan sulfate proteoglycans, or HSPGs, that are specifically modified and broadly expressed on many tumors. AU-011, our first VDC candidate, is being developed for the first line treatment of primary choroidal melanoma, a rare disease with no drugs approved. We have completed a Phase 1b/2 trial using intravitreal administration that has demonstrated a statistically significant growth rate reduction in patients with prior active growth and high levels of tumor control with visual acuity preservation in a majority of patients, as assessed using clinical endpoints in alignment with feedback from the U.S. Food and Drug Administration, or the FDA. These data supported advancement into a Phase 2 dose escalation trial, where we are currently evaluating suprachoroidal, or SC, administration of AU-011. We plan to present six to twelve month safety and efficacy data from this trial in 2022, and, if favorable, initiate a pivotal trial in the second half of 2022. We are also developing AU-011 for additional ocular oncology indications and plan to file an IND in the United States in second half of 2022 for choroidal metastases. Leveraging our VDCs’ broad tumor targeting capabilities, we also plan to initiate a Phase 1a trial in non-muscle invasive bladder cancer, or NMIBC, our first non-ophthalmic solid tumor indication, in the second half of 2022 and present Phase 1a data from this trial in 2023.

### Our VDC Platform

VDCs are a novel class of drugs with a dual mechanism of action that promotes cancer cell death by both the delivery of the cytotoxic payload to generate acute necrosis and by activating a secondary immune mediated response. VDCs are analogous to antibody-drug conjugates, or ADCs, another technology that employs a targeting moiety and a cytotoxic payload. We believe that our VDC platform has the potential to serve as a backbone for a broad portfolio of targeted oncology therapeutics and has the following potential key advantages:

1. A single VDC can deliver hundreds of cytotoxic molecules conjugated to its capsid proteins.
2. Based on the ability of VLPs to selectively recognize specifically modified and overexpressed HSPGs present on a large number of tumor types, VDCs have the potential to be used broadly across a wide range of cancers with limited off-target toxicity.
3. The VDCs have a high number of HSPG binding sites and this multi-valency permits the strong and selective binding to tumor cells.
4. VDCs have a dual mechanism of action, first by acute necrosis of the tumor cells, and subsequently by creating a highly immunogenic milieu that induces an antitumor specific immune response leading to a more robust and durable therapy.

## Our Pipeline

Our goal is to leverage our platform to develop a new class of targeted therapies that bring therapeutic benefit to multiple cancer indications, initially focusing on the field of ocular oncology. Our next area of focus, bladder cancer, is one of the most expensive cancers to treat on a per patient basis, and global market for bladder cancer is expected to reach \$4.0 billion by 2028 across the United States, EU5, and Japan. To date, we have produced a VDC, AU-011, which we are advancing in multiple indications, as shown in the pipeline below.

Program		Preclinical	Phase 1	Phase 2	Pivotal	Upcoming Milestones
Ocular Oncology	<b>Primary Choroidal Melanoma</b> (Ph1b/2 Intravitreal and Ph2 Suprachoroidal)	[Progress bar spanning Preclinical, Phase 1, and Phase 2]				<ul style="list-style-type: none"> <li>• YE 2024 – Initial Phase 2a safety data</li> <li>• 2022 – Phase 2a safety and efficacy data</li> <li>• 2H 2022 – Initiate Phase 2b (pivotal trial)</li> </ul>
	<b>Choroidal Metastasis</b> (Breast, lung and other cancer metastasis in the eye)	[Progress bar in Preclinical]				<ul style="list-style-type: none"> <li>• 2H 2022 – IND</li> </ul>
	<b>Other Cancers of the Ocular Surface</b> (e.g., SCC, Melanoma)	[Progress bar in Preclinical]				
Other Solid Tumors	<b>Non-Muscle Invasive Bladder Cancer</b>	[Progress bar in Preclinical]				<ul style="list-style-type: none"> <li>• 2H 2022 – Initiate Phase 1a trial</li> <li>• 2023 – Phase 1a data</li> </ul>
	<b>Other HSPG-Expressing Tumors</b> (e.g., Cutaneous Melanoma, HNSCC)	[Progress bar in Preclinical]				

## Our Solution – AU-011

AU-011 consists of an HPV-derived VLP conjugated to hundreds of infrared laser-activated molecules. The VDC is designed in a way that prevents the conjugation from interfering with tumor binding enabling its selectivity to specifically modified HSPGs on tumor cells but not to normal cells. Laser activation of AU-011 is designed to result in precise tumor cell killing with minimal damage to surrounding healthy tissues. In the absence of AU-011 activation or binding to the tumor cell membrane, there is no cytotoxic effect. Multiple laser treatments, following a single dose of AU-011, increase antitumor activity because of the reoxygenation of the tumor and the photostability of AU-011. Finally, acute necrosis triggers immunogenic cell death leading to the generation of an adaptive, long-term antitumor immune response.

### **AU-011 for Ocular Oncology**

We are initially developing AU-011 for the treatment of primary choroidal melanoma, a vision- and life-threatening ocular cancer for which there are currently no drugs approved. Choroidal melanoma is the most common intraocular cancer in adults, with an incidence of 11,000 patients/year in the United States and Europe. It is estimated that 96% of patients are diagnosed early without clinical evidence of metastatic disease. However, despite the current treatments with radiotherapy the long-term prognosis is poor with death occurring in more than 50% of cases. We intend to develop AU-011 as a first line therapy to treat early-stage disease which includes small melanomas and indeterminate lesions representing approximately 9,000 patients/year in the United States and Europe. AU-011 has been granted Orphan Drug designation for treatment of uveal melanoma and Fast Track designation for the treatment of choroidal melanoma by the FDA.

In our completed Phase 1b/2 trial, AU-011, administered by intravitreal injection, was well-tolerated and demonstrated high levels of local tumor control while preserving vision at twelve months in patients that had prior active tumor growth. The therapeutic regimen of AU-011 achieved tumor shrinkage or a near-zero growth rate in majority of patients and was associated with preservation of visual acuity in 71% of patients at twelve months. We are currently conducting a Phase 2 dose escalation trial of AU-011 with SC administration. We intend to initiate the first pivotal trial in the second half of 2022. Because our mechanism of action preserves key ocular structures, we also intend to develop AU-011 for additional ocular oncology indications, beginning with choroidal metastases.

### **AU-011 for NMIBC**

In addition, we are developing AU-011 for the treatment of NMIBC. Bladder cancer is the most common malignancy involving the urinary system and is the eighth most common cause of cancer death in men in the United States. While metastatic bladder cancer has several approved therapies, there are very limited options for the treatment of NMIBC. We are planning to initiate clinical development of AU-011 with intramural administration, a novel route of administration, for the treatment of patients with intermediate and high-risk bladder cancer lesions. This novel route of administration is intended to place high levels of the drug at the base of the tumor where laser activation of AU-011 can cause necrosis and prevent residual tumor cells from further growth and recurrence. We have generated preclinical *in vivo* data that supports that our dual mechanism of action can lead to cytotoxicity and long-term antitumor immunity which may further reduce the risk of metastases. We believe this immune response can play an even larger role in bladder cancer, given that bladder cancer has a well-documented response to immune activation. We are conducting IND-enabling studies with AU-011 and intend to begin clinical trials in second half of 2022 and present Phase 1a data from this trial in 2023.

### **Our Strategy**

Our goal is to leverage our proprietary platform to develop a new class of targeted therapies that bring therapeutic benefit to a broad range of cancer indications with high unmet need where we believe we can establish a new standard of care. The key elements of our strategy include:

- Advance AU-011 through late-stage clinical development and, if approved, commercialization for the first line treatment of primary choroidal melanoma.
- Continue developing AU-011 for additional ocular oncology indications, starting with choroidal metastases.
- Pursue development of AU-011 for our first non-ophthalmic solid tumor indication in NMIBC.
- Broaden the application of our proprietary technology platform to expand our pipeline of product candidates.
- Evaluate and selectively enter into strategic collaborations to maximize the potential of our pipeline and accelerate the development of our programs.

### **Our Team**

Our team has extensive experience in the development of drugs in oncology and ophthalmology. Our CEO and founder, Elisabet de los Pinos, PhD, MBA, was previously part of the marketing team that led the European commercialization of Alimta® for the treatment of lung cancer at Eli Lilly. Cadmus Rich, MD, MBA, CPE, our Chief Medical Officer, a board-certified ophthalmologist, has extensive experience in leading ophthalmology research and development at companies including Inotek, IQVIA and Alcon/Novartis. Julie Feder, our CFO, previously served as CFO at Verastem Oncology, the Clinton Health Access Initiative and was instrumental in the integration of Genzyme and Sanofi. Mark De Rosch, PhD, our COO, was previously the Chief Regulatory Officer at Epizyme during which time Epizyme received FDA accelerated approval of its first product in two oncology indications. Christopher Primiano, our CBO, led multiple strategic transactions during his prior tenure as CBO and General Counsel at Karyopharm Therapeutics, Inc., a commercial oncology company. The Chairman of our Board of Directors is David Johnson, the former Chief Executive Officer at VelosBio Inc., a clinical-stage oncology company developing novel ADCs and bispecific antibodies that was acquired by Merck in 2020 for \$2.75 billion. Prior to founding VelosBio Inc. he was the Chief Executive Officer at Acerta Pharma B.V. leading to its acquisition by AstraZeneca plc for \$7 billion.

### **Risks Associated with our Business**

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section titled "Risk Factors," immediately following this prospectus summary. These risks include the following, among others:

- We are heavily dependent on the success of AU-011, our only product candidate to date.
- We have incurred significant net losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for AU-011, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.
- 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 or terminate one or more of our research and development programs, future commercialization efforts, product development or other operations.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our objectives relating to the discovery, development and commercialization of our product candidates.
- We have not yet successfully initiated or completed any pivotal clinical trials nor commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects.
- If we fail to develop additional product candidates, our commercial opportunity could be limited.
- AU-011 is a biologic that requires the use of a device, which may result in additional regulatory risks.
- Interim, "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.
- AU-011 or any future product candidates may cause or reveal significant adverse events, toxicities or other undesirable side effects which may delay or prevent marketing approval. In addition, if we obtain approval for any of our product candidates, significant adverse events, toxicities or other undesirable side effects may be identified during post-marketing surveillance, which could result in regulatory action or negatively affect our ability to market the product.
- We may incur additional costs or experience delays in initiating or completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- The COVID-19 pandemic, or a similar pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.
- We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.
- Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

- We currently rely on third-party contract manufacturing organizations, or CMOs, for the production of clinical supply of AU-011 and may continue to rely on CMOs for the production of commercial supply of AU-011, if approved. This reliance on CMOs increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.
- If AU-011 or any future product candidates do not achieve broad market acceptance, the revenue that we generate from their sales may be limited, and we may never become profitable.
- Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.
- Our ability to compete may decline if we do not adequately protect our proprietary rights, and our proprietary rights do not necessarily address all potential threats to our competitive advantage.
- Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of product candidates, prohibit our use of proprietary technology or sale of potential products or put our patents and other proprietary rights at risk.
- If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to pursue our business strategy will be impaired, could result in loss of markets or market share and could make us less competitive.

#### **Impact of COVID-19**

The COVID-19 pandemic continues to present a substantial public health and economic challenge around the world, and to date has led to the implementation of various responses, including government-imposed quarantines, stay-at-home orders, travel restrictions, mandated business closures and other public health safety measures.

We continue to closely monitor the impact of the COVID-19 pandemic on all aspects of our business, including how it has and will continue to impact our operations and the operations of our suppliers, vendors and business partners, and may take further precautionary and preemptive actions as may be required by federal, state or local authorities. In addition, we have taken steps to minimize the current environment's impact on our business and strategy, including devising contingency plans and securing additional resources from third party service providers. For the safety of our employees and families, we have introduced enhanced safety measures for scientists to be present in our labs and increased the use of third party service providers for the conduct of certain experiments and studies for research programs. To date, we've only encountered minor delays in our manufacturing process due to a supply chain constraint with one of our vendors.

Beyond the impact on our pipeline, the extent to which COVID-19 ultimately impacts our business, results of operations and financial condition will depend on future developments, which remain highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the emergence of new variants, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions taken to contain COVID-19 or treat its impact, including vaccination campaigns, among others. If we or any of the third parties with whom we engage, however, were to experience any additional shutdowns or other prolonged business disruptions, our ability to conduct



our business in the manner and on the timelines presently planned could be materially or negatively affected, which could have a material adverse impact on our business, results of operations and financial condition. Although to date, our business has not been materially impacted by COVID-19, it is possible that our clinical development timelines could be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition and results of operations. See “Risk Factors” for a discussion of the potential adverse impact of the COVID-19 pandemic on our business, financial condition and results of operations.

### **Corporate History**

We were incorporated under the laws of the State of Delaware in January 2009. Our principal corporate office is located at 85 Bolton Street, Cambridge, MA 02140, and our telephone number is (617) 500-8864. Our website address is [www.aurabiosciences.com](http://www.aurabiosciences.com). We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus.

We own various U.S. federal trademark applications and unregistered trademarks, including our company name. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the symbols ® and ™, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

### **Implications of Being an Emerging Growth Company and a Smaller Reporting Company**

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to only disclose 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;
- reduced disclosure about our executive compensation arrangements;
- not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved; and
- an exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the fifth anniversary of our initial public offering or such earlier time that we are no longer an emerging growth company. We would 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 revenue of \$1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (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 Securities and Exchange Commission, or SEC, which means the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. We are in the process of evaluating

the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation, providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act.

We are also a "smaller reporting company" as defined under the Securities Act and Exchange Act. We may continue to be a smaller reporting company so long as either (i) the market value of shares of our common stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of shares of our common stock held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and have reduced disclosure obligations regarding executive compensation, and, similar to emerging growth companies, if we are a smaller reporting company under the requirements of (ii) above, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

## THE OFFERING

Common stock offered by us	5,400,000 shares.
Common stock to be outstanding immediately after this offering	28,409,613 shares (29,219,613 shares if the underwriters exercise their over-allotment option in full).
Over-allotment option	We have granted the underwriters an option, exercisable for 30 days after the date of this prospectus, to purchase up to 810,000 additional shares from us.
Use of proceeds	We estimate that our net proceeds to us from the sale of shares of our common stock in this offering will be approximately \$67.3 million, or \$77.9 million if the underwriters exercise in full their over-allotment option, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to advance the clinical development of AU-011 for the treatment of choroidal melanoma and NMIBC, to develop our platform and for general corporate purposes. See "Use of Proceeds" for additional information.
Risk factors	You should carefully read the "Risk Factors" section of this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
Nasdaq Global Market symbol	AURA

The number of shares of our common stock to be outstanding after this offering is based on 23,009,613 shares of our common stock outstanding as of June 30, 2021, which assumes the automatic conversion of all of our outstanding shares of preferred stock into an aggregate of 22,550,561 shares of common stock upon the completion of this offering, and excludes:

- 2,908,580 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2021, at a weighted average exercise price of \$4.66 per share;
- 3,352,166 shares of our common stock reserved for future issuance under our 2021 Stock Option and Incentive Plan, or 2021 Plan, which became effective on the date immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, including (i) 994,901 shares of our common stock issuable upon the exercise of stock options to be granted to certain employees, including our named executive officers, (ii) 232,111 shares of common stock issuable upon the vesting of restricted stock units, or RSUs, to be granted to

certain employees, including our named executive officers and (iii) 72,000 shares of our common stock issuable upon the exercise of stock options granted to our non-employee directors, in each case granted upon the effectiveness of the registration statement of which this prospectus forms a part and with an exercise price equal to the initial public offering price per share; and

- 335,217 shares of our common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan, or ESPP, which became effective on the date immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part.

Except as otherwise indicated, all information in this prospectus assumes or gives effect to:

- the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 22,550,561 shares of our common stock immediately prior to the completion of this offering;
- the issuance of 173,827 shares of Series B convertible preferred stock upon the exercise of the outstanding preferred stock warrants subsequent to June 30, 2021, which will convert into 12,686 shares of our common stock upon completion of this offering;
- the issuance and sale of 3,649 shares of common stock on August 2, 2021 to Elisabet de los Pinos, our CEO, pursuant to an option exercise, with an exercise price of \$5.48 per common share.
- the issuance and sale of 2,190 and 1,459 shares of common stock on October 5, 2021 to a holder of our convertible preferred stock, pursuant to an option exercise, with an exercise price of \$5.75 and \$5.48 per share of common stock, respectively.
- except as expressly outlined above, no exercise of the outstanding options described above;
- no exercise by the underwriters of their option to purchase up to an additional 810,000 shares of our common stock in this offering;
- a one-for-13.7 reverse split of our common stock, which became effective on October 22, 2021, and a corresponding adjustment in the ratio at which our outstanding preferred stock is convertible into common stock; and
- the filing of our tenth amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, which will occur immediately prior to the completion of this offering.

### SUMMARY FINANCIAL DATA

You should read the following summary financial data together with our financial statements and the related notes appearing elsewhere in this prospectus and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. We have derived the statement of operations data for the years ended December 31, 2020 and 2019 from our audited financial statements appearing elsewhere in this prospectus. The statement of operations data for the six months ended June 30, 2021 and 2020 and the balance sheet data as of June 30, 2021 have been derived from our unaudited financial statements appearing elsewhere in this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited data reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the financial information in those statements. Our historical results are not necessarily indicative of results that should be expected in any future period, and our results for any interim period are not necessarily indicative of results that should be expected for any full year. The summary financial data included in this section are not intended to replace the audited financial statements and the related notes included elsewhere in this prospectus and are qualified in their entirety by the financial statements and the related notes included elsewhere in this prospectus.

	For the Six Months Ended June 30,		For the Year Ended December 31,	
	2021	2020	2020	2019
	(unaudited)			
	(In thousands, except share and per share data)			
<b>Statement of Operations Data:</b>				
Research and development expenses	\$ 10,817	\$ 11,649	\$ 18,042	\$ 19,617
General and administrative	3,911	2,017	4,164	4,523
Total operating expenses	14,728	13,666	22,206	24,140
Loss from operations	(14,728)	(13,666)	(22,206)	(24,140)
Other expenses, net				
Change in fair value warrant liability	1	—	3	(44)
Change in fair value of derivative liability	(52)	—	—	—
Interest income (expense), including amortization of discount	3	(2)	(3)	(5)
Loss from disposal of assets	(3)	—	—	(11)
Total other expenses, net	(51)	(2)	—	(60)
<b>Net loss and comprehensive loss</b>	<b>\$ (14,779)</b>	<b>\$ (13,668)</b>	<b>\$ (22,206)</b>	<b>\$ (24,200)</b>
Net loss per share attributable to common stockholders, basic and diluted(1)	\$ (49.49)	\$ (49.27)	\$ (82.06)	\$ (89.36)
Weighted average shares used to compute net loss per share attributable to common stockholders, basic and diluted	419,059	355,657	367,204	338,289
Pro forma net loss per share of common stock attributable to common stockholders (unaudited), basic and diluted(2)	\$ (0.76)		\$ (1.60)	
Pro forma weighted average shares of common stock (unaudited), basic and diluted(2)	19,565,548		13,893,556	

(1) See Note 13 to our financial statements appearing elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share.

- (2) The unaudited pro forma basic and diluted weighted-average shares of common stock outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the six months ended June 30, 2021 and year ended December 31, 2020 have been prepared to reflect (i) the issuance of 173,827 shares of Series B convertible preferred stock upon the exercise of the outstanding preferred stock warrants subsequent to June 30, 2021, which will convert into 12,686 shares of our common stock upon completion of this offering, and (ii) the automatic conversion of all shares of our convertible preferred stock, including the preferred stock warrants described above in (i), into common stock immediately prior to the closing of this offering, as if this offering had occurred on the later of the beginning of each period or the issuance date of the convertible preferred stock.

The following table sets forth summary balance sheet data as of June 30, 2021:

- on an actual basis;
- on a pro forma basis to give effect to (i) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 22,550,561 shares of common stock immediately prior to the completion of this offering; (ii) the issuance of 173,827 shares of Series B convertible preferred stock upon the exercise of the outstanding preferred stock warrants subsequent to June 30, 2021, which will convert into 12,686 shares of our common stock upon completion of this offering; (iii) the issuance and sale of 3,649 shares of common stock on August 2, 2021 to Elisabet de los Pinos, our CEO, pursuant to an option exercise, with an exercise price of \$5.48 per share; (iv) the issuance and sale of 2,190 and 1,459 shares of common stock on October 5, 2021 to a holder of our convertible preferred stock, pursuant to an option exercise, with an exercise price of \$5.75 and \$5.48 per share of common stock, respectively; and (v) the filing and effectiveness of our tenth amended and restated certificate of incorporation upon the closing of this offering; and
- on a pro forma as adjusted basis to give effect to (i) the pro forma adjustments described above and (ii) our issuance and sale of 5,400,000 shares of common stock in this offering at the initial public offering price of \$14.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	As of June 30, 2021		
	Actual (unaudited)	Pro Forma (unaudited)	Pro Forma as Adjusted (unaudited)
	(in thousands)		
<b>Balance Sheet Data:</b>			
Cash	\$ 92,197	\$ 92,453	\$ 160,081
Working capital(1)	87,559	87,815	155,498
Total assets	98,653	98,909	166,202
Warrant liability	71	-	-
Derivative liability	52	52	52
Convertible preferred stock	215,304	-	-
Total stockholders' equity (deficit)	(122,751)	92,880	160,228

- (1) We define working capital as current assets less current liabilities.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully read and consider all of the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. Unless otherwise indicated, references to our business being harmed in these risk factors will include harm to our business, reputation, financial condition, results of operations and future prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.*

### **Risks Related to Our Financial Position, and Additional Capital Needs**

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

Investment in biotechnology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or fail to become commercially viable. Our net losses were \$14.8 million and \$13.7 million for the six months ended June 30, 2021 and 2020, respectively, and \$22.2 million and \$24.2 million for the years ended December 31, 2020 and 2019, respectively. As of June 30, 2021, we had an accumulated deficit of \$131.7 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect our research and development expenses to increase significantly as we continue clinical development for AU-011 and continue to discover and develop additional product candidates. In addition, if we obtain regulatory approval for our product candidates, we will incur significant sales, marketing and manufacturing expenses. After this offering, we will incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. We have no products approved for commercial sale and therefore have never generated any revenue from product sales, and we do not expect to in the foreseeable future. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from any product sales. We have no products approved for commercial sale, and do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our success in achieving a number of goals, including:

- initiating and completing research regarding, and preclinical and clinical development of, AU-011 in primary choroidal melanoma and, additional oncology indications, other research programs from our VDC technology platform and any future product candidates;
- obtaining marketing approval for AU-011 and any future product candidates for which we complete clinical trials;

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- transferring our manufacturing process to a commercial contract development and manufacturing organization for AU-011 and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;
- launching and commercializing AU-011 and any future product candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor;
- obtaining market acceptance of AU-011 and any future product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates from our VDC technology platform;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- obtaining, maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if AU-011 or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate.

If we are successful in obtaining regulatory approvals to market AU-011 or any future product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, the labels for AU-011 and any future product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***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 or terminate one or more of our research and development programs, future commercialization efforts, product development or other operations.***

Since our inception, we have used substantial amounts of cash to fund our operations, and our expenses will increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we continue the research and development of, initiate and complete clinical trials of, and seek marketing approval for AU-011. Identifying and developing pharmaceutical products, including



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conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Even if one or more of AU-011 or any future product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the EMA, or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we are currently conducting or anticipate. Other unanticipated costs may also arise. Because the design and outcome of our current and planned clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of AU-011 or any future product candidates that 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 continue our operations.

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 operating expenses and capital expenditures into 2024. Advancing the development of AU-011 and other research programs will require a significant amount of capital. The net proceeds from this offering, together with our existing cash and cash equivalents, will not be sufficient to fund AU-011 through regulatory approval, and we anticipate needing to raise additional capital to complete the development of and commercialize AU-011. Our estimate as to how long we expect our existing cash and cash equivalents, together with the net proceeds from this offering, to fund our operations 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.

We will be required to obtain further funding through public or private equity financings, debt financings, collaborative agreements, licensing arrangements or other sources of financing, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Any additional fundraising efforts may divert our management from their day to day activities, which may adversely affect our ability to develop and commercialize product candidates. Disruptions in financial markets in general or more recently due to the COVID-19 pandemic may make equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. To the extent that we raise additional capital through the sale of equity or convertible debt securities, each investor's ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect each investor's rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates 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. Attempting to secure additional financing may divert our management from our day to day activities, which may adversely affect our ability to commercialize AU-011 if and when approved and develop our product candidates.

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 clinical trials, research and development programs, future commercialization efforts or other operations.

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

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient product or royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, existing stockholder ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek commercial or development partners for our lead products or any future product candidate at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves.

***Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our objectives relating to the discovery, development and commercialization of our product candidates.***

We rely on our team's expertise in drug discovery, translational research and patient-driven precision medicine to develop our product candidates. Our business depends significantly on the success of this engine and the development and commercialization of the product candidates that we discover with this engine. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales in the near term, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives, including:

- successful and timely completion of preclinical and clinical development of AU-011 in primary choroidal melanoma and additional oncology indications, other research programs from our VDC technology platform, and any other future programs;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development of AU-011, other research programs from our VDC technology platform, and any other future programs;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- Transferring our manufacturing process to a commercial CDMO, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;

- a continued acceptable safety profile following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- satisfying any required post-marketing approval commitments to applicable regulatory authorities;
- identifying, assessing and developing new product candidates from our VDC technology platform;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- defending against third-party interference or infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

### **Risks Related to the Discovery and Development of our Product Candidates**

#### ***We are heavily dependent on the success of AU-011, our only product candidate to date.***

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to development of AU-011 in multiple oncology indications, which is currently our only product candidate. Accordingly, our business currently depends heavily on the successful development, regulatory approval, and commercialization of AU-011. We can provide no assurance that AU-011 will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. If we were required to discontinue development of AU-011 or if AU-011 does not receive regulatory approval or fails to achieve significant market acceptance, we would be delayed by many years in our ability to achieve profitability, if ever.

The research, testing, manufacturing, safety, efficacy, recordkeeping, labeling, approval, licensure, sale, marketing, advertising, promotion and distribution of AU-011 is, and will remain, subject to comprehensive regulation by the FDA and foreign regulatory authorities. Failure to obtain regulatory approval for AU-011 in the United States, Europe and other major markets around the world will prevent us from commercializing and marketing AU-011 in such jurisdictions.

Even if we were to successfully obtain approval from the FDA and foreign regulatory authorities for AU-011, any approval might contain significant limitations related to use, including limitations on the stage or type of cancer AU-011 is approved to treat, as well as restrictions for specified age groups, warnings, precautions or contraindications, or requirement for a risk evaluation and mitigation strategy, or REMS. Any such limitations or restrictions could similarly impact any supplemental marketing approvals we may obtain for AU-011. Furthermore, even if we obtain regulatory approval for AU-011,

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we will still need to develop a commercial infrastructure or develop relationships with collaborators to commercialize, establish a commercially viable pricing structure and obtain coverage and adequate reimbursement from third-party payors, including government healthcare programs. If we, or any future collaborators, are unable to successfully commercialize AU-011, we may not be able to generate sufficient revenue to continue our business.

***If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for AU-011, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.***

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

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted Investigational New Drug application, or IND, Premarket Approval, or PMA, biologics license application, or BLA, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Because the activity of AU-011 in ocular melanoma requires a drug delivery device and activation by a laser, the regulatory complexity of the product candidate is greater than for products that don't utilize a device, which creates uncertainties in the requirements for regulatory approval. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

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- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities or those of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process, as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

Our VDC product candidates are based on a technology that we are in the process of developing. We expect the novel nature of such product candidates to create further challenges in obtaining regulatory approval. As a result, our ability to develop product candidates and obtain regulatory approval may be significantly impacted.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop based on the completed clinical trials. Additionally, due to the COVID-19 pandemic, the conduct of Advisory Committee meetings may be disrupted or delayed and the impact that may have on the overall timing of regulatory approvals is uncertain.

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

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

***We have not yet successfully initiated or completed any pivotal clinical trials nor commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects.***

Our operations to date have been limited to financing and staffing our company, developing our technology and conducting preclinical research and Phase 1 and Phase 2 clinical trials for our product candidates, primarily related to our AU-011 program. We have not yet demonstrated an ability to successfully initiate or complete pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Furthermore, we may conduct our first pivotal trial based on an adaptive design, which could increase the time spent on or costs

associated with this trial. We are in the process of transferring our intended commercial manufacturing process to our intended external contract development and manufacturing organization, or CDMO, commercial manufacturing site. During this transfer process, some modifications may be needed to ensure manufacturability and ability to scale-up the process to commercial batch sizes. We intend to perform an analytical comparability assessment between the current clinical process and the intended commercial process, however, if this analytical process comparability assessment is unsuccessful, clinical comparability may be required, which may result in delayed regulatory approval. We do not anticipate a change in formulation. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by clinical-stage biopharmaceutical companies such as ours. Any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

***If we fail to develop additional product candidates, our commercial opportunity could be limited.***

We expect to focus our resources on the development of AU-011 in the near term. Developing, obtaining marketing approval for, and commercializing any future product candidates will require substantial additional funding and will be subject to the risks of failure inherent in drug product development. We cannot assure you that we will be able to successfully advance any future product candidates through the development process.

Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market any future product candidates for any indication, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity may be limited and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

***AU-011 is a biologic that requires the use of a device, which may result in additional regulatory risks.***

AU-011 is a novel biologic for which the intended use requires activation by a laser, which is regulated as a medical device. We plan to file a single BLA for the review and approval of this combination in our initial target indication of choroidal melanoma, but subsequent indications and delivery systems may require different or additional applications for marketing authorization. There may be additional regulatory risks for biologic-device combination products. We may experience delays in obtaining regulatory approval of AU-011 given the increased complexity of the review process when approval of the product and a delivery device is sought under a single marketing application. In the United States, each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic or device. The laser component will be subject to FDA design control device requirements which comprise among other things, design verification, design validation, and testing to assess performance, cleaning, and robustness. Delays in or failure of the studies conducted by us, or failure of our company, our collaborators, if any, or our third-party providers or suppliers to maintain compliance with regulatory requirements could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in AU-011 reaching the market.

***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development

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program, such as manufacturing methods and formulation, may be altered along the way in an effort to optimize processes and results. For example, we are planning to use Phase 2 drug product to initiate our first pivotal study and transitioning to the intended commercial drug product as soon as it is available to conduct the second planned pivotal study. Such changes to a product candidate carry the risk that they will not achieve the intended objectives of optimizing the performance of the candidate. Any such changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities, or as needed to provide appropriate statistical power for a given trial.

In addition, our competitors may in the future commence clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may choose instead to enroll in clinical trials of our competitors. Furthermore, our ability to enroll patients may be significantly delayed by the evolving COVID-19 pandemic, and we cannot accurately predict the extent and scope of such delays at this point. Additionally, the process of finding patients may prove costly. We also may not be able to identify, recruit or enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidates under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. Our lead indication of Choroidal Melanoma is a rare disease and as such clinical trial recruitment estimates may be inaccurate and such recruitment may take longer than expected.

Patient enrollment may be affected by other factors, including:

- the severity of the disease under investigation;
- clinicians' and patients' awareness of, and perceptions as to the potential advantages and risks of AU-011 in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- the efforts to obtain and maintain patient consents and facilitate timely enrollment in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion;
- competing studies or trials with similar eligibility criteria;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- reporting of the preliminary results of any of our clinical trials; and
- factors we may not be able to control, including the impacts of the COVID-19 pandemic, that may limit patients, principal investigators or staff or clinical site availability.

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

We may in the future choose to conduct one or more clinical trials outside the United States, including in Europe. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practices, or GCP, regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

***Even if we receive marketing approval for our current or future product candidates in the United States, we may never receive regulatory approval to market our current or future product candidates outside of the United States.***

We plan to seek regulatory approval of our current or future product candidates outside of the U.S. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction.

For example, even if the FDA grants marketing approval of a product candidate, we may not obtain approvals in other jurisdictions, and 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 marketing approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among countries and can involve additional product candidate testing and administrative review periods different from those in the United States. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval. The marketing approval processes in other countries generally implicate all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. In particular, in many countries outside of the U.S., products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries.

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 products in certain countries. If we or any future collaborator fail to comply with regulatory requirements in international markets or fail to receive applicable marketing approvals, it would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.



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

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials. AU-011 and any other product candidates we may develop may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. For example, AU-011 may not be effective at slowing or arresting tumor growth or may not preserve visual acuity in later stage trials. Even if AU-011 successfully slows or arrests tumor growth, this may not result in overall improved patient survival. Additionally, any positive results generated in our ongoing clinical trials and preclinical studies would not ensure that we will achieve similar results in larger, pivotal clinical trials or in clinical trials of AU-011 in broader patient populations. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Furthermore, the failure of any product candidate to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of any other product candidates then under development and/or cause the FDA or other regulatory authorities to require additional testing before approving any other product candidates.

***As an organization, we have never conducted pivotal clinical trials, and we may be unable to do so for any product candidates we may develop.***

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA, the EMA, or other regulatory agencies to market AU-011 or any future product candidate. Carrying out later-stage clinical trials is a complicated process. As an organization, we have not previously conducted any later stage or pivotal clinical trials. In order to do so, we will need to expand our clinical development and regulatory capabilities, and we may be unable to recruit and train qualified personnel. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to approval of AU-011 or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates.

***Interim, “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, interim or top-line data from our clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular 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 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. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. 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. Adverse differences between interim data and final data could materially affect our business, financial condition, results of operations and growth prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general. Further, additional disclosure of interim data by us or by our potential competitors in the future could result in volatility in the price of our common stock. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or top-line data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize our product candidates may be harmed, which could materially affect our business, financial condition, results of operations and growth prospects.

Additionally, we may utilize “open-label” trial designs or open-label extensions to our clinical trials in the future. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial or extension may not be predictive of future clinical trial results with AU-011 when studied in a controlled environment with a placebo or active control.

***AU-011 or any future product candidates may cause or reveal significant adverse events, toxicities or other undesirable side effects which may delay or prevent marketing approval. In addition, if we obtain approval for any of our product candidates, significant adverse events, toxicities or other undesirable side effects may be identified during post-marketing surveillance, which could result in regulatory action or negatively affect our ability to market the product.***

Adverse events or other undesirable side effects caused by or associated with treatment by AU-011 or our future product candidates 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. Although AU-011 has been evaluated in clinical trials, unexpected side effects may still arise in our ongoing or any future clinical trials. These side effects have included pigmentary changes around the tumor margin and vision loss.

During the conduct of clinical trials, subjects report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other

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adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. Many times, side effects are only detectable after investigational products are tested in large-scale, pivotal clinical trials or, in some cases, after they are made available to subjects on a commercial scale after approval.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product or require additional warnings on the label;
- additional clinical trials or post-approval studies;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- regulatory authorities may require additional warnings or limitations in the labeling, such as a contraindication, limitation of use, or a boxed warning, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be subject to regulatory investigations and government enforcement actions; and
- our reputation may suffer.

Moreover, if AU-011 or any of our future product candidates is associated with undesirable or unexpected side effects in clinical trials, we may elect to abandon or limit their 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, which may limit the commercial expectations for the product candidate, even if it is approved.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could materially affect our business, financial condition, results of operations, and growth prospects.

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

We may experience delays in initiating or completing our preclinical studies or clinical trials, including as a result of delays in obtaining, or failure to obtain, the FDA's clearance to initiate clinical trials under future INDs. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will not require redesign, will enroll an adequate number of subjects on time, or will be completed on schedule, if at all. We may experience numerous unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that require us to modify the design or implementation of our preclinical studies or clinical trials or to delay or terminate a clinical trial;
- regulators or institutional review boards, or IRBs, or ethics committees may delay or may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective clinical research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

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- preclinical studies or clinical trials of our product candidates may fail to show safety or efficacy or otherwise produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, or we may decide to abandon product research or development programs;
- preclinical studies or clinical trials of our product candidates may not produce differentiated or clinically significant results across tumor types or indications;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, be unable to provide us with sufficient product supply to conduct or complete preclinical studies or clinical trials, fail to meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators or IRBs or ethics committees may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our clinical trials are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- clinical trials of our product candidates may be delayed due to complications associated with the evolving COVID-19 pandemic;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates; and
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination or clinical hold due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, adverse findings upon an inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA may disagree with our clinical trial design or our interpretation of data from clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

Moreover, principal investigators for our trials involving AU-011 or any future clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal

investigator has created a conflict of interest or otherwise affected the interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site, and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

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

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

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, monitoring, and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, compliance with applicable product tracking and tracing requirements, as well as continued compliance with current Good Manufacturing Practices, or cGMPs, and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- clinical trial holds;

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- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Additionally, the FDA and other regulatory agencies closely regulate the post-approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other regulatory agencies impose stringent restrictions on manufacturers' communications regarding off-label use. 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 do not market our medicines for their approved indications, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. Violation of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws. The 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 our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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 our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

***We may be unable to obtain orphan drug designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that

the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if our current product candidates and any future product candidates receive orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We have obtained orphan designation for AU-011 for the treatment of uveal melanoma, and we may seek additional orphan drug designations for some or all of our current or future product candidates in orphan indications in which there is a medically plausible basis for the use of these products. Even if we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

The FDA may reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

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

We may seek breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We have obtained fast track designation for AU-011 for the treatment of choroidal melanoma, and we may seek additional fast track designations for other product candidates we may develop. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the drug or biologic demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation,

we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

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

We may seek accelerated approval of our current or future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate FDA approval.

### **Risks Related to Our Reliance on Third Parties**

***We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.***

We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct some aspects of our research, preclinical testing and clinical trials. We plan to use a clinical CRO for at least part of the potentially pivotal trial for AU-011 for the treatment of choroidal melanoma. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, our product development activities would be delayed.

Our reliance on these third parties for research and development activities reduces our control over these activities, but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial, as well as the applicable legal, regulatory and scientific standards. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. We are also required to register ongoing clinical trials and to post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Due to the rarity of ocular melanomas, we may engage clinical trial sites that have little experience in the conduct of clinical trials under GCPs. Even though we train the clinical trial sites, monitor the activities, and perform quality audits to assess and ensure compliance, we cannot ensure such compliance.



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Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other biological product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

***We currently rely on third-party contract manufacturing organizations, or CMOs, for the production of clinical supply of AU-011 and may continue to rely on CMOs for the production of commercial supply of AU-011, if approved. This reliance on CMOs increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.***

We currently do not have any manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. Instead, we expect to rely on third parties for the manufacture of our product candidates and related raw materials for future pre-clinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. We are currently reliant on a single source for each of our regulatory starting materials, drug substance and drug product manufacturing for AU-011.

We or our third-party suppliers or manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredient, or API, necessary to produce AU-011 and future product candidates we may develop in the quantities needed for our clinical trials or, if AU-011 or any future product candidates we may develop are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or APIs, including shortages caused by the purchase of such raw materials or API, by our competitors or others. Even if raw materials or API are available, we may be unable to obtain sufficient quantities at an acceptable cost or quality. The failure by us or our third-party suppliers or manufacturers to obtain the raw materials or API necessary to manufacture sufficient quantities of AU-011 or any future product candidates we may develop could delay, prevent or impair our development efforts and may have a material adverse effect on our business. To date, we have only encountered minor delays in our manufacturing process due to a supply chain constraint with one of our vendors

Reliance on third party manufacturers may expose us to different risks than if we were to manufacture clinical or commercial supply of our product candidates ourselves. The facilities used by third-party manufacturers to manufacture AU-011 or any future product candidates must be authorized by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of drug products and other laws and regulations. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. Some of our contract manufacturers may not have produced a commercially-approved product and therefore may not have

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obtained the requisite FDA approvals to do so. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we generally have not, and do not intend to, begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates. Additionally, any changes implemented by a new CMO could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of AU-011 and future product candidates and jeopardize our ability to commence product sales and generate revenue.

As part of their manufacture of our product candidates, our CMOs and third-party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes, misappropriates or otherwise violates the intellectual property or proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against applicable claims, either of which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, 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 clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, we may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms.

Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- lack of qualified backup suppliers for those components or materials that are currently purchased from a sole or single source supplier;
- failure to manufacture our product according to our schedule or at all;
- production difficulties caused by unforeseen events that may delay the availability of one or more of the necessary raw materials or delay the manufacture of AU-011 or any future product candidates for use in clinical trials or for commercial supply, including as a result of the COVID-19 pandemic;
- supply or service disruptions or increased costs that are beyond our control;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

AU-011 and any other product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. Additionally, three vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020 and early 2021, and more may be authorized in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time-consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or on terms acceptable to us. Our current and anticipated future dependence upon others for the manufacture of AU-011 or any other future product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

### **Risks Related to Commercialization**

***If AU-011 or any future product candidates do not achieve broad market acceptance, the revenue that we generate from their sales may be limited, and we may never become profitable.***

We have never commercialized a product candidate for any indication. Even if AU-011 and any future product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we may not generate significant revenue and may not become profitable or may be significantly delayed in achieving profitability. Market acceptance of AU-011 and any future product candidates by the medical community, patients and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients, and patients may be reluctant to switch, from existing therapies even when new and potentially more effective or safer treatments enter the market. If public perception is influenced by claims that the use of virus-like drug conjugates, or VDCs, is unsafe, whether related to our or our competitors' products, our products may not be accepted by the general public or the medical community. In addition, training clinicians to properly use AU-011 or any future product candidate that requires a similar laser and microinjector may create reluctance by clinicians to adopt our products, potentially adversely affecting our future sales and marketing efforts. Furthermore, such training increases our costs to generate sales associated with any such product. Future adverse events in targeted oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments.

Efforts to educate the medical community and third-party payors on the benefits of AU-011 and any future product candidates may require significant resources and may not be successful. If AU-011 or any future product candidates are approved but do not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree

of market acceptance of any of AU-011 and any future product candidates will depend on a number of factors, including:

- the efficacy of AU-011 and our virus-like particle, or VLP, technology, and any future product candidates;
- the prevalence and severity of adverse events associated with AU-011 and any future product candidates or those products with which they may be co-administered;
- the clinical indications for which AU-011 are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling or those of comparable foreign regulatory authorities, including potential limitations or warnings for AU-011 and any future product candidates that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for AU-011 and any future product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of AU-011 and any future product candidates and any products with which they are co-administered;
- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third party payors, including government healthcare programs such as Medicare and Medicaid and other healthcare payors;
- the price concessions required by third-party payors to obtain coverage;
- the perception of physicians, patients, third-party payors and others in the medical community of the relative safety, efficacy, convenience, effect on quality of life and cost effectiveness of AU-011 compared to those of other available treatments;
- the willingness of patients to pay out-of-pocket in the absence of adequate coverage and reimbursement;
- the extent and strength of our marketing and distribution of AU-011 and any future product candidates;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to AU-011 and any future product candidates or to which we agree as part of a REMS or voluntary risk management plan;
- the timing of market introduction of AU-011 and any future product candidates, as well as competitive products;
- our ability to offer AU-011 and any future product candidates for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- the publicity concerning our AU-011 or competing products and treatments;
- the actions of companies that market any products with which AU-011 and any future product candidates may be co-administered;
- the approval of other new products;
- adverse publicity about AU-011 and any future product candidates or any products with which they are co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

***We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.***

We have never commercialized a product candidate and we currently have no sales, marketing or distribution capabilities and have no experience in marketing products. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring the rights to our product candidate and undertaking preclinical studies and clinical trials of our product candidate. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. We may not be successful in transitioning from a company with a development focus to a company capable of supporting commercial activities.

In addition to establishing internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. Further, if we enter into arrangements with third parties to perform sales and marketing services, our product revenues, if any, may be lower than if we were to market and sell any products that we develop ourselves. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

Furthermore, developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidate. We may not be able to build an effective sales and marketing organization in the United States, the EU or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidate, we may have difficulties generating revenue from them.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

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

The biopharmaceutical industry is characterized by intense competition and rapid innovation. While we are not aware of anyone currently developing a treatment for choroidal melanoma, in the future our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results than us. There are multiple companies that have drugs in clinical development for the treatment of NMIBC that are unresponsive to Bacillus Calmette-Guerin, such as Sesen Bio, Inc., FerGene, Inc., UroGen Pharma Ltd., CG Oncology, Inc. and ImmunityBio, Inc. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our potential competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that our product candidates are also focused on treating. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical

industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaboration partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products, which may reduce or eliminate our commercial opportunity. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

Even if we obtain regulatory approval of our product candidates, the availability and price of our potential future competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. For additional information regarding our competition, see "Business—Competition."

***Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.***

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize any products that we may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

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

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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 medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs, or VA, hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if approved.

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

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States, particularly in light of the most recent presidential election, 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, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

***If the market opportunity for AU-011 is smaller than we estimate or if any regulatory approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.***

The incidence and prevalence for target patient populations of AU-011 and any future product candidates has not been established with precision. AU-011 is a virus-like drug conjugate product candidate being developed for the first line treatment of primary choroidal melanoma. Our projections of both the number of people who have choroidal melanoma, as well as additional ocular oncology and bladder cancer indications, are based on our estimates.

The total addressable market opportunity will ultimately depend upon, among other things, the patient criteria included in the final label, the indications for which AU-011 is approved for sale, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients with choroidal melanoma, choroidal metastases and NMIBC for which AU-011 may be approved as treatment may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. AU-011 is our only product candidate and therefore our business is dependent on the market opportunity for our product.

***Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.***

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchase, lease, order, arrangement, or recommendation of any good,

facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties;

- the federal civil and criminal false claims laws and Civil Monetary Penalties Law, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity 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 of 2009, or HITECH, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created 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, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- the United States Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program, with



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specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals beginning in 2022 (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists & anesthesiologist assistants, and certified nurse-midwives), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018 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. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal,

civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

***Current and future healthcare legislative reform measures may have a material adverse effect on our business and results of operations.***

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

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed on procedural grounds the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an Executive Order that initiated a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

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

Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologics based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. On December 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction against implementation of the interim final rule. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Model interim final rule shall not commence earlier than sixty (60) days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that it will continue to seek new legislative measures to control drug costs. For example, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices.

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Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030, unless additional Congressional action is taken. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic.

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

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

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current or future product candidates or additional pricing pressures. In particular any policy changes through CMS as well as local state Medicaid programs could have a significant impact on our business.

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

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

- the demand for our current or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;

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- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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

***Our ability to compete may decline if we do not adequately protect our proprietary rights, and our proprietary rights do not necessarily address all potential threats to our competitive advantage.***

Our commercial success depends upon obtaining and maintaining proprietary rights to our intellectual property estate, including rights relating to our technology platform using HPV-derived virus-like particles to target tumors and VDCs like AU-011, as well as successfully defending these rights against third-party challenges and successfully enforcing these rights to prevent third-party infringement. We will only be able to protect AU-011 or a future product candidate derived from our platform from unauthorized use by third parties to the extent that valid and enforceable patents cover it. Our ability to maintain patent protection for AU-011 or a future product candidate is uncertain due to a number of factors, including that:

- others may design around our patent claims to produce competitive technologies, products or methods that fall outside of the scope of our patents;
- we may not obtain patent protection in all jurisdictions that may eventually provide us a significant business opportunity; and
- any patents issued to us may be successfully challenged by third parties.

Even with our patents covering AU-011, we may still not be able to make use or sell AU-011 or a future product candidate because of the patent rights of others. Others may have filed patent applications covering compositions, products or methods that are similar or identical to ours, which could materially affect our ability to successfully commercialize AU-011 or a future product candidate.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited.

Obtaining and maintaining a patent portfolio entails significant expense, including periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications. These expenditures can be at numerous stages of prosecuting patent applications and over the lifetime of maintaining and enforcing issued patents. We may or may not choose to pursue or maintain protection for particular intellectual property in our portfolio. If we choose to forgo patent protection or to allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. Furthermore, we employ reputable law firms and other professionals to help us comply with the various procedural, documentary, fee payment and other similar provisions

we are subject to and, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Legal action that may be required to enforce our patent rights can be expensive and may involve the diversion of significant management time. There can be no assurance that we will have sufficient financial or other resources to file and pursue infringement claims, which typically last for years before they are concluded. In addition, these legal actions could be unsuccessful and result in the invalidation of our patents, a finding that they are unenforceable or a requirement that we enter into a licensing agreement with or pay monies to a third party for use of technology covered by our patents. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents, or have used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to successfully protect or enforce our intellectual property rights, our competitive position could suffer, which could harm our results of operations.

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

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development of AU-011 or any future product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize AU-011 or any future product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

The growth of our business may depend in part on our ability to acquire, in-license or use third-party proprietary rights. We may be unable to acquire or in-license any such proprietary rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

***We rely on intellectual property licensed from third parties. We face risks with respect to such reliance, including the risk that, 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.***

We are a party to a number of intellectual property license agreements that are important to our business. Our existing license agreements impose on us various diligence, milestone payment, royalty and other obligations. If we fail to comply with any of our obligations under these agreements, or we are subject to a bankruptcy, our licensors may have the right to terminate the license, in which event we would not be able to market any products covered by the license.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted and related obligations under the license agreement and other interpretation-related issues;
- our licensor's right to license or sublicense patent and other rights to us, and whether and the extent to which the right is retained by a third party;
- whether and the extent to which our technology infringes on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of AU-011 or any future product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

In addition, disputes may arise regarding the payment of the royalties due to licensors in connection with our exploitation of the rights we license from them. Licensors may contest the basis of royalties we retained and claim that we are obligated to make payments under a broader basis. Such disputes may be costly to resolve and may divert management's attention away from day-to-day activities. In addition to the costs of any litigation we may face, any legal action against us could increase our payment obligations under the respective agreement and require us to pay interest and potentially damages to such licensors. If disputes over intellectual property that we have licensed from third parties prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we or our collaborators may be unable to successfully manufacture and commercialize AU-011 or a future product candidate.

If we fail to comply with our obligations under the license agreements, our licensors may have the right to terminate these agreements, in which event we might not be able to manufacture or market AU-011 or a future product candidate. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

***If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation with respect to our AU-011 or a future product candidate, thereby potentially extending the term of marketing exclusivity for such product, our business may be harmed.***

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our owned, co-owned, or in-licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. The Hatch-Waxman Act allows a

maximum of one patent to 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. In the European Union, AU-011 or a future product candidate may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

***Patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.***

The patent positions of biopharmaceutical and biotechnology companies and other actors in our fields of business can be highly uncertain and typically involve complex scientific, legal and factual analyses. In particular, the interpretation and breadth of claims allowed in some patents covering biopharmaceutical compositions may be uncertain and difficult to determine and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the U.S. Patent and Trademark Office, or the USPTO, and its foreign counterparts are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference or derivation proceedings, and U.S. patents may be subject to reexamination proceedings, post-grant review and/or *inter partes* review in the USPTO. International patents may also be subject to opposition or comparable proceedings in the corresponding international patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, derivation, reexamination, post-grant review, *inter partes* review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

Furthermore, even if not challenged, our patents and patent applications may not prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to AU-011 or a future product candidate is threatened, it could dissuade companies from collaborating with us to develop, and could threaten our or their ability to successfully commercialize, AU-011 or a future product candidate.

In addition, changes in, or different interpretations of, patent laws in the United States and other countries may permit others to use our discoveries or to develop and commercialize our technology without providing any compensation to us, may limit the scope of patent protection that we are able to obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights.



***Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of product candidates, prohibit our use of proprietary technology or sale of potential products or put our patents and other proprietary rights at risk.***

Our commercial success depends upon our ability to develop, manufacture, market and sell AU-011 or a future product candidate without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the biotechnology industry is common, including patent infringement lawsuits, interferences, oppositions, reexamination proceedings, post-grant review, and/or *inter partes* review before the USPTO and corresponding international patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. As a result of any patent infringement claims, or in order to avoid any potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights. These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing AU-011 or a future product candidate, or forced to modify AU-011 or a future product candidate, or to cease some aspect of our business operations, which could harm our business significantly. We might also be forced to redesign or modify our technology or product candidates so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Further, if a patent infringement suit is brought against us or our third-party service providers, our development, manufacturing or sales activities relating to AU-011 or a future product candidate that is the subject of the suit may be delayed or terminated. In addition, defending such claims may cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third party's patent rights. These damages potentially could include increased damages and attorneys' fees if we are found to have infringed such rights willfully. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. In addition, if the breadth or strength of protection provided by the patents and patent applications we own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We may in the future be subject to third-party claims and similar adversarial proceedings or litigation in other jurisdictions regarding our infringement of the patent rights of third parties. Even if such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to further develop or commercialize AU-011 or a future product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable.

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If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering our technology or a product candidate, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and Europe, defendant counterclaims alleging invalidity or unenforceability are common. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part of the patent protection on AU-011 or a future product candidate.

***We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.***

Filing, prosecuting and defending patents on AU-011 or a future product candidate in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

We have and have applied for patents in those countries where we intend to make, have made, use, offer for sale or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but where our ability to enforce our patent rights is not as strong as in the United States. These products may compete with any products that we may develop, and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. 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 chose 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 or biotechnologies. As a result, many companies have encountered significant difficulties in protecting and defending intellectual property rights in certain jurisdictions outside the United States. Such issues may make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights.

Furthermore, proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, subject our patents to the risk of being invalidated or interpreted narrowly, subject our patent applications to the risk of not issuing or 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 to us, if any, may not be

commercially meaningful, while the damages and other remedies we may be ordered to pay such third parties may be significant. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

***If we or our licensors are unable to protect the confidentiality of the proprietary information related to our product or process, our business and competitive position would be harmed.***

We and our licensors rely on confidentiality agreements to protect unpatented know-how, technology and other proprietary information related to our product and process, to maintain our competitive position. For example, our licensor Li-Cor maintains its manufacture of IRDye 700DX<sup>®</sup> dye molecules (used in AU-011) as a trade secret. Trade secrets and know-how can be difficult to protect. In particular, the trade secrets and know-how in connection with our development programs and other proprietary technology we may develop may over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel with scientific positions in academic and industry.

We seek to protect our proprietary information, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information. 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 any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated proprietary information 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 are unwilling to protect trade secrets.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing AU-011. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our therapeutic programs and other proprietary technologies we may develop. Such an outcome could have a materially adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our proprietary information. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our proprietary information were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or

misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

***If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to pursue our business strategy will be impaired, could result in loss of markets or market share and could make us less competitive.***

Our ability to compete in the highly competitive biopharmaceutical industries depends upon our ability to attract, manage, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements for these individuals could harm our business. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Competition for skilled personnel in our industry is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, in a timely manner or at all. In particular, we have experienced a very competitive hiring environment in Cambridge, Massachusetts, where we are headquartered. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity incentive awards that vest over time. The value to employees of restricted stock awards and stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams are at-will employees and may terminate their employment with us on short notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Given the stage of our programs and our plans to expand operations, our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior personnel across our organization.

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

Public health crises such as pandemics or similar outbreaks could adversely impact our business. Recently, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes COVID-19 has spread to most countries across the world, including all 50 states within the U.S., including Cambridge, Massachusetts, where our primary

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office and laboratory space is located. The coronavirus pandemic is evolving, and has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which the coronavirus impacts our operations or those of our third party partners, including our preclinical studies or clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the coronavirus, the emergence of new variance, acceptance of vaccines and the actions to contain the coronavirus or treat its impact, among others. The continued spread of COVID-19 globally could adversely impact our preclinical or clinical trial operations in the U.S., including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. For example, similar to other biopharmaceutical companies, we may experience delays in initiating IND-enabling studies, protocol deviations, enrolling our clinical trials, or dosing of patients in our clinical trials as well as in activating new trial sites. COVID-19 may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. Any negative impact COVID-19 has to patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Additionally, timely enrollment in planned clinical trials is dependent upon clinical trial sites which could be adversely affected by global health matters, such as pandemics. We plan to conduct clinical trials for our product candidates in geographies which are currently being affected by the COVID-19 pandemic. Some factors from the COVID-19 pandemic that will delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

- the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials;
- limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;
- the potential negative affect on the operations of our third-party manufacturers;
- interruption in global shipping affecting the transport of clinical trial materials, such as drug product and conditioning drugs and other supplies used in our clinical trials;
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments;
- operations, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors;
- changes in local regulations as part of a response to the COVID-19 pandemic, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether; and
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines.

We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring certain of our employees to work remotely, suspending all non-essential travel worldwide for our employees and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business. We cannot presently predict the scope and severity of the planned and potential shutdowns or disruptions of businesses and government agencies, such as the Securities and Exchange Commission, or the SEC, or FDA. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. As of May 2021, certain inspections, such as foreign preapproval, surveillance, and for-cause inspections that are not deemed mission-critical, remain temporarily postponed. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates and in May 2021 announced plans to continue progress toward resuming standard operational levels. Should FDA determine that an inspection is necessary for approval of and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

These and other factors arising from COVID-19 could worsen in countries that are already afflicted with COVID-19 or could continue to spread to additional countries. Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of operation and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our programs and product candidates.

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

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

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

***Changes in tax laws or in their implementation or interpretation may adversely affect us or our investors.***

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

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

***Our internal information technology systems, or those of our third-party CROs, contractors, consultants or others who process sensitive information on our behalf, may fail or suffer security incidents, loss or leakage of data and other compromises, any of which could result in a material disruption of our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing such information, expose us to liability or otherwise adversely affect our business.***

In the ordinary course of our business, we may collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information (including health information). It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such information. We also have outsourced certain of our operations to third parties, and as a result we manage a number of third parties who have access to our information. Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyberattacks by sophisticated nation-state and nation-state supported actors or by malicious third parties (including the deployment of harmful malware (such as malicious code, viruses and worms), natural disasters, global pandemics, fire, terrorism, war and telecommunication and electrical failures, fraudulent activity, as well as security incidents from inadvertent or intentional actions (such as error or theft) by our employees, contractors, consultants, business partners, and/or other third parties, phishing attacks, ransomware, denial-of-service attacks, social engineering schemes and other means that affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure as well as lead to unauthorized access, disclosure or acquisition of information. Cyberattacks are increasing in their frequency, sophistication and intensity. The techniques used to sabotage or to obtain unauthorized access to our information technology systems or those upon whom we rely to process our information change frequently, and we may be unable to anticipate such techniques or implement adequate preventative measures or to stop security incidents in all instances. The recovery systems, security protocols, network protection mechanisms and other security measures that we have integrated into our information technology systems, which are designed to protect against, detect and minimize security breaches, may not be adequate to prevent or detect service interruption, system failure or data loss.

Significant disruptions of our information technology systems or security incidents could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information including health information), and could result in financial, legal, business and reputational harm to us. If such disruptions were to occur and cause interruptions in our operations, it could result in a material

disruption of our product development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Further, the COVID-19 pandemic has resulted in a significant number of our employees and partners working remotely, which increases the risk of a data breach or issues with data and cybersecurity. To the extent that any disruption or security incident results in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our future product candidates could be delayed.

We may also be required to comply with laws, regulations, rules, industry standards, and other legal obligations that require us to maintain the security of personal data. We may also have contractual and other legal obligations to notify collaborators, our clinical trial participants, or other relevant stakeholders of security incidents. Failure to prevent or mitigate cyberattacks could result in unauthorized access to data, including personal data. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security breaches involving certain types of data. Such disclosures are costly, could lead to negative publicity, may cause our collaborators or other relevant stakeholders to lose confidence in the effectiveness of our security measures and require us to expend significant capital and other resources to respond to and/or alleviate problems caused by the actual or perceived security breach. In addition, the costs to respond to a cybersecurity event or to mitigate any identified security vulnerabilities could be significant, including costs for remediating the effects of such an event, paying a ransom, restoring data from backups, and conducting data analysis to determine what data may have been affected by the breach. In addition, our efforts to contain or remediate a security incident or any vulnerability exploited to cause an incident may be unsuccessful, and efforts and any related failures to contain or remediate them could result in interruptions, delays, harm to our reputation, and increases to our insurance coverage.

In addition, litigation resulting from security breaches may adversely affect our business. Unauthorized access to our information technology systems could result in litigation with our collaborators, our clinical trial participants, or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices in response to such litigation, which could have an adverse effect on our business. If a security breach were to occur and the confidentiality, integrity or availability of our data or the data of our collaborators were disrupted, we could incur significant liability, which could negatively affect our business and damage our reputation.

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



***We are, or may become, subject to stringent and changing privacy and information security laws, regulations, standards, policies and contractual obligations related to data privacy and security. Our actual or perceived failure to comply with such data privacy and security obligations could lead to government enforcement actions (which could include civil or criminal fines or penalties), a disruption of our clinical trials or commercialization of our products, private litigation, changes to our business practices, increased costs of operations, and adverse publicity that could otherwise negatively affect our operating results and business. Compliance or the failure to comply with such obligations could increase the costs of our products, could limit their use or adoption, and could otherwise negatively affect our operating results and business.***

Regulation of data (including personal and clinical trial data) is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. Moreover, we are subject to the terms of our privacy and security policies, representations, certifications, standards, publications, contracts and other obligations to third parties related to data privacy, security and processing. These and other requirements could require us or our collaborators to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our collaborators' ability to process or use data in order to support the provision of our products, affect our or our collaborators' ability to offer our products in certain locations, cause regulators to reject, limit or disrupt our clinical trial activities, result in increased expenses, reduce overall demand for our products, and make it more difficult to meet expectations of relevant stakeholders.

We and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations including, without limitation, laws that regulate personal data such as health data. For example, in the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state personal information laws (e.g., the California Consumer Privacy Act of 2018, or CCPA), state data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act), govern the collection, use, disclosure and protection of health-related and other personal data. These laws and regulations could apply to our operations, the operations of our collaborators, or other relevant stakeholders upon whom we depend. In addition, we may obtain personal data (including health information) from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. Additionally, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

The CCPA became effective on January 1, 2020 and gives California residents expanded rights to access and delete their personal data, opt out of certain personal data sharing and receive detailed information about how their personal data is used. The CCPA requires covered businesses to provide new disclosures to California residents. 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. Although there are limited exemptions for clinical trial data and the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, the CCPA may increase our compliance costs and potential liability. It is anticipated that the CCPA will be expanded on

January 1, 2023, when the California Privacy Rights Act of 2020, or CPRA, becomes operative. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive information, establish restrictions on the retention of personal data, expand the types of data breaches subject to the CCPA's private right of action and establish a new California Privacy Protection Agency to implement and enforce the new law. In addition, other states have enacted or proposed data privacy laws. For example, Virginia recently passed its Consumer Data Protection Act and Colorado recently passed the Colorado Privacy Act, both of which differ from the CPRA and go into effect in 2023. These laws demonstrate our vulnerability to the evolving regulatory environment related to personal data. As we expand our operations, these and similar laws may increase our compliance costs and potential liability.

Foreign data protection laws, such as, without limitation, the EU's GDPR and EU member state implementing legislation, may also apply to health-related and other personal data that we process, including, without limitation, personal data relating to clinical trial participants. European data protection laws impose strict obligations on the ability to process health-related and other personal data of European data subjects, including in relation to security (which requires the adoption of administrative, physical and technical safeguards designed to protect such information), collection, use and transfer of personal data. European data protection laws may affect our use, collection, analysis, and transfer (including cross-border transfer) of such personal data. These include, without limitation, several requirements relating to transparency related to communications with data subjects regarding the processing of their personal data, obtaining the consent of the individuals to whom the personal data relates, limitations on the retention of personal data, increased requirements pertaining to health data, establishing a legal basis for processing, notification of data processing obligations or security incidents to the competent national data protection authorities and/or data subjects, the security and confidentiality of the personal data, various rights that data subjects may exercise with respect to their personal data, and strict rules and restrictions on the transfer of personal data outside of Europe (including from the European Economic Area (EEA), Switzerland and United Kingdom).

European data protection laws prohibit, without an appropriate legal basis, the transfer of personal data to countries outside of Europe, such as to the United States, which are not considered relevant authorities to provide an adequate level of data protection. A decision by the Court of Justice of the European Union, or the "Schrems II" ruling, invalidated the EU-U.S. Privacy Shield Framework, and raised questions about whether the European Commission's Standard Contractual Clauses, or SCCs, one of the primary alternatives to the Privacy Shield, can lawfully be used for personal data transfers from Europe to the United States or most other countries. Similarly, the Swiss Federal Data Protection and Information Commissioner recently opined that the Swiss-U.S. Privacy Shield is inadequate for transfers of personal data from Switzerland to the United States. The United Kingdom, whose data protection laws are similar to those of the European Union, has similarly determined that the EU-U.S. Privacy Shield is not a valid mechanism for lawfully transferring personal data from the United Kingdom to the United States. Use of the SCCs must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular, applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place. However, the nature of these additional measures is currently uncertain. Additionally, the European Commission recently adopted new SCCs that will repeal the SCCs adopted under the Data Protection Directive. This means we may need to update our contracts that involve the transfer of personal data outside of the EEA to the new SCCs. As supervisory authorities issue further guidance on personal data export mechanisms, including on the new SCCs, and/or start taking enforcement action, our compliance costs could increase, we may be subject to 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 conduct clinical trials, this could negatively impact our business.

Further, the UK's decision to leave the EU, often referred to as Brexit, and ongoing developments in the UK have created uncertainty regarding data protection regulation in the UK. Following December 31, 2020, and the expiry of transitional arrangements between the UK and EU, the data protection obligations of the GDPR continue to apply to UK-related Processing of personal data in substantially unvaried form under the so-called "UK GDPR" (i.e., the GDPR as it continues to form part of UK law by virtue of section 3 of the EU (Withdrawal) Act 2018, as amended). However, going forward, there is increasing risk for divergence in application, interpretation and enforcement of the data protection laws as between the UK and EEA. Furthermore, the relationship between the UK and the EEA in relation to certain aspects of data protection law remains uncertain, including with respect to regulation of data transfers between EU member states and the UK. On June 28, 2021, the European Commission issued an adequacy decision under the GDPR which allows transfers (other than those carried out for the purposes of United Kingdom immigration control) of personal data from the EEA to the UK to continue without restriction for a period of four years ending June 27, 2025. After that period, the adequacy decision may be renewed, but, only if the UK continues to ensure an adequate level of data protection. During these four years, the European Commission will continue to monitor the legal situation in the UK and could intervene at any point if the UK deviates from the level of data protection in place at the time of issuance of the adequacy decision. If the adequacy decision is withdrawn or not renewed, transfers of personal data from the EEA to the UK will require a valid 'transfer mechanism' and we may be required to implement new processes and put new agreements in place, such as SCCs, to enable transfers of personal data from the EEA to the UK to continue.

The increase of foreign privacy and security legal frameworks with which we must comply, increases our compliance burdens and exposure to substantial fines and penalties for non-compliance. For example, under the GDPR, entities that violate the GDPR can face fines of up to the greater of 20 million euros or 4% of their worldwide annual turnover (revenue). Additionally, regulators could prohibit our use of personal data subject to the GDPR. The GDPR has increased our responsibility and potential liability in relation to personal data that we process, requiring us to put in place additional mechanisms to comply with the GDPR and other foreign data protection requirements.

We may also publish privacy policies and other documentation regarding our collection, processing, use and disclosure of personal data and/or other confidential information. Although we endeavor to comply with our published policies and documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or contractors fail to comply with our published policies and documentation. Such failures can subject us to potential foreign, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices.

Compliance with U.S. federal and state as well as foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure, or perceived failure, to comply with federal, state and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties, fines or penalties), private litigation, a diversion of management attention, adverse publicity and negative effects on our operating results and business. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or data protection obligations related to information security or security breaches. Moreover, clinical trial participants or subjects about whom we or our collaborators obtain information, as well as the providers who share this information with us, may limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, contracts or privacy notices or breached other obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

Compliance

with data protection laws may be time consuming, require additional resources and could result in increased expenses, reduce overall demand for our products and make it more difficult to meet expectations of or commitments to our relevant stakeholders.

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

Our operations, and those of our contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, pandemics 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 and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

***Any future acquisitions, in-licensing or strategic partnerships may increase our capital requirements, dilute our stockholders, divert our management's attention, cause us to incur debt or assume contingent liabilities and subject us to other risks.***

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product candidates and initiatives in pursuing such an acquisition or strategic partnership;
- spend substantial operational, financial and management resources in integrating new businesses, technologies and products;
- 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 regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

***We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, or that otherwise

disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. For example, following Hurricane Maria, shortages in production and delays in a number of medical supplies produced in Puerto Rico resulted, and any similar interruption due to a natural disaster affecting us or any of our third-party manufacturers could materially delay our operations.

***We expect to significantly expand our organization, including building sales and marketing capability and creating additional infrastructure to support our operations as a public company, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of sales and marketing and finance and accounting. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and our limited experience in managing such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert or stretch our management and business development resources in a way that we may not anticipate. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any current or future product candidates that we may develop.***

We will face an inherent risk of product liability exposure related to the testing of our current or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any current or future product candidates that we may develop. Claims could also be asserted under the state consumer production acts. If we cannot successfully defend ourselves against claims that our current or future product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

We do not yet maintain product liability insurance, and we anticipate that we will need to increase our insurance coverage when we begin clinical trials and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain product liability insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

***Our employees and independent contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.***

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; United States federal and state fraud and abuse laws, data privacy and security laws and other similar non-United States laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third-parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other United States federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

**Risks Related to Our Common Stock and This Offering**

***A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.***

Based on shares outstanding as of June 30, 2021, upon completion of this offering, we will have outstanding a total of 28,409,613 shares of common stock. Of these shares, only 5,400,000 shares of common stock sold in this offering, or 6,210,000 shares if the underwriters exercise their option to purchase 810,000 additional shares in full, will be freely tradable, without restriction, in the public market immediately after this offering. Each of our officers and directors and substantially all our stockholders have entered into lock-up agreements with the underwriters that restrict their ability to sell or transfer their shares. The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. However, the representatives of our underwriters may, in their sole discretion, permit our officers, directors and other current stockholders who are subject to the contractual lock-up to sell shares prior to the expiration of the lock-up agreements. After this 180-day period, based on shares outstanding as of June 30, 2021, up to an additional 22,864,652 shares of common stock will be eligible for sale in the public market, approximately 33% of which are held by our officers, directors and their affiliated entities, and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or Securities Act. In addition, 2,908,580 shares of our common stock that are subject to outstanding options as of June 30, 2021 and 252,721 shares of our common

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stock that are subject to options granted after June 30, 2021 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act.

After this offering, the holders of an aggregate of 22,832,468 shares of our outstanding common stock as of June 30, 2021 will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. We also intend to register shares of common stock that we may issue under our equity incentive plans. Once we register these shares, they will be able to be sold freely in the public market upon issuance, subject to the 180-day lock-up period under the lock-up agreements described above and in the section entitled "Underwriting." The representatives of the underwriters may release some or all of the shares of common stock subject to lock-up agreements at any time and without notice, which would allow for earlier sales of shares in the public market.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, could adversely affect the market price of our common stock, even if our business is doing well.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. To the extent that the additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

Based on the beneficial ownership of our common stock as of June 30, 2021, prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 76.2% of our common stock and, upon the completion of this offering, that same group will hold approximately 62.2% of our outstanding common stock (assuming no exercise of the underwriters' option to purchase additional shares, no exercise of outstanding options and no purchases of shares in this offering by any of this group), in each case assuming the conversion of all outstanding shares of our redeemable convertible preferred stock into shares of our common stock and the net exercise of warrants outstanding that would otherwise expire upon the completion of this offering. As a result, these stockholders, if acting together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate

transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

***If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.***

You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. Assuming that the underwriters do not exercise their option to acquire additional common stock in this offering, you will experience immediate dilution of \$8.40 per share in net tangible book value of the common stock, representing the difference between the initial public offering price of \$14.00 per share and our pro forma as adjusted net tangible book value per share as of June 30, 2021. In addition, investors purchasing common stock in this offering will contribute 25.7% of the total amount invested by stockholders since inception but will only own 19.0% of the shares of common stock outstanding. In the past, we issued options and other securities to acquire common stock at prices significantly below the initial public offering price. To the extent these outstanding securities are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. In addition, if the underwriters exercise their option to purchase additional shares, or outstanding options and warrants are exercised, you could experience further dilution. See "Dilution" for a more detailed description of the dilution you will experience immediately after this offering.

***We have broad discretion in how we use the proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.***

We will have considerable discretion in the application of the net proceeds of this offering. We intend to use the net proceeds from this offering to fund clinical development of AU-011 and to fund new and ongoing research activities, working capital and other general corporate purposes, which may include funding for the hiring of additional personnel, capital expenditures and the costs of operating as a public company. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value. For a further description of the use of proceeds from this offering, please refer to the section entitled "Use of Proceeds."

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the ownership of its equity over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of this offering or subsequent shifts in our stock ownership, some of which are outside our control. Our net operating losses and tax credits may also be impaired or restricted under state law. As of December 31, 2020,



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we had federal net operating loss carryforwards of approximately \$106.1 million, and state net operating loss carryforwards of \$89.3 million. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As a result, the amount of the net operating loss and tax credit carryforwards presented in our financial statements could be limited and may expire unutilized. Under current law, unused U.S. federal net operating loss carryforwards generated in taxable years beginning after December 31, 2017 are not subject to expiration and may be carried forward indefinitely. For taxable years beginning after December 31, 2020, however, the deductibility of such U.S. federal net operating losses is limited to 80% of our taxable income in such taxable years.

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

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

***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. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

***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:

- variations in the level of expense related to the ongoing development of AU-011 or future development programs;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us, or existing or future collaborators or licensing partners;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- 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 any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results 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 common 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 amended and restated bylaws to be effective upon the consummation of this offering designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.***

Pursuant to our amended and restated bylaws that will become effective upon the completion of this offering, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, or our amended and restated certificate of incorporation or our amended and restated bylaws (including the interpretation, validity or enforceability thereof) or (iv) any action asserting a claim that is governed by the internal affairs doctrine (the Delaware Forum Provision). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws will further provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the Federal Forum Provision). In addition, our amended and restated bylaws that will become effective upon the completion of this offering will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

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

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 harm our business.

***Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management and, therefore, decrease the trading price of our common stock.***

Our fourth amended and restated certificate of incorporation and amended and restated bylaws, which are to become effective at or prior to the completion of this offering, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

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

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

## General Risks

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

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

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

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

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, academic collaborators, partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA, EMA and comparable foreign regulatory authorities, provide true, complete and accurate information to the FDA, EMA and comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. We

have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, academic collaborators, partners and vendors, and the precautions we take to detect and prevent such activities 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 actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations.

***An active and liquid trading market for our common stock may not develop and you may not be able to resell your shares of common stock at or above the public offering price.***

Prior to this offering, no market for shares of our common stock exists and an active trading market for our shares may never develop or be sustained following this offering. The initial public offering, or IPO, price for our common stock was determined 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 IPO 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 IPO 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 or products by using our shares of common stock as consideration.

***We are an “emerging growth company” and a “smaller reporting company” and we cannot be certain if the reduced reporting requirements applicable to “emerging growth companies” and “smaller reporting 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 JOBS Act. For as long as we continue to be an “emerging growth company,” we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) not being required to comply with the independent auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (3) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an “emerging growth company,” we are only required to provide two years of audited financial statements and two years of selected financial data in our periodic reports.

We will remain an “emerging growth company” until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a “large accelerated filer,” which requires the market value of our common stock that is held by non-affiliates to exceed \$700.0 million as of the prior June 30, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

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 exemptions

from disclosure requirements, including not being required to comply with the independent auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. 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 share price may be more volatile.

Under the JOBS Act, “emerging growth companies” can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an “emerging growth company” or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than \$700.0 million and our annual revenue is less than \$100.0 million during the most recently completed fiscal year. We may continue to be a “smaller reporting company” until (i) the market value of our stock held by non-affiliates is less than \$250.0 million or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700.0 million as of the prior June 30th. If we are a “smaller reporting company” at the time we cease to be an “emerging growth company,” we may continue to rely on exemptions from certain disclosure requirements that are available to “smaller reporting companies.” Specifically, as a “smaller reporting company” we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, “smaller reporting companies” have reduced disclosure obligations regarding executive compensation.

***The market 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. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including the other risks described in this section of the prospectus entitled “Risk Factors” and the following:

- results of preclinical studies and results or enrollment of clinical trials of AU-011 or our future product candidates, or those of our potential future competitors or our existing or future collaborators;
- the impact of the COVID-19 pandemic on our employees, trials, collaboration partners, suppliers, our results of operations, liquidity and financial condition;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates;
- the success of future competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical trials, manufacturing process or sales and marketing terms;

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- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for AU-011 or our future product candidates and products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters, pandemics and other calamities; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. 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.

In the past, securities class action litigation has often been brought against public companies following declines in the market price of their securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and our resources, which could harm our business.

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

As a public company, and particularly after we are no longer an “emerging growth company,” we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act and rules implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our products once commercialized. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an “emerging growth company,” we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. In addition, for as long as we are a “smaller reporting company” with less than \$100 million in annual revenue, we would be exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404(b) of the of the Sarbanes-Oxley Act of 2002. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

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

Upon completion of this offering, we will become subject to the periodic reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act. We have 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.



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However, 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 will be 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.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and “Business,” contains express or implied forward-looking statements that are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

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

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

In some cases, you can identify forward-looking statements by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled “Risk Factors” and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement, of which this prospectus forms a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

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

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 investors are cautioned not to unduly rely upon these statements.

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

## USE OF PROCEEDS

We estimate that our net proceeds from the sale of 5,400,000 shares of our common stock in this offering will be approximately \$67.3 million, or \$77.9 million if the underwriters exercise in full their option to purchase additional shares, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We currently expect to use our net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- \$50.0 million to \$60.0 million to advance the clinical development of AU-011 for the treatment of choroidal melanoma and NMIBC, including:
  - data readout of the Phase 2a SC choroidal melanoma trial
  - data readout of the Phase 1a NMIBC trial
  - initial data readout of the Phase 2b pivotal trial in choroidal melanoma
- \$5.0 million to \$10.0 million to develop our platform; and
- the remaining proceeds for general corporate purposes, which may include the hiring of additional personnel, capital expenditures and the costs of operating as a public company.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above and we expect that we will require additional funds in order to fully accomplish the specified uses of the proceeds of this offering. We may also use a portion of the net proceeds to in-license, acquire, or invest in complementary businesses or technologies to continue to build our pipeline, research and development capabilities and our intellectual property position, although we currently have no agreements, commitments, or understandings with respect to any such transaction.

Based on our current plans, we believe that our existing cash and cash equivalents, together with the anticipated net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements into 2024. The expected net proceeds from this offering will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

Due to the many inherent uncertainties in the development of our programs and product candidates, the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our research and development, the timing of patient enrollment and evolving regulatory requirements, the timing and success of preclinical studies, our ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions, any strategic alliances that we may enter into with third parties for our product candidates or strategic opportunities that become available to us, and any unforeseen cash needs.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term and long-term interest-bearing instruments, investment-grade securities, and direct or guaranteed obligations of the U.S. government. We cannot predict whether the proceeds invested will yield a favorable return. Our management will retain broad discretion in the application of the net proceeds we receive from our initial public offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

## DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant. Investors should not purchase our common stock with the expectation of receiving cash dividends.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2021:

- on an actual basis;
- on a pro forma basis to give effect to (i) the conversion of all outstanding shares of our preferred stock into an aggregate of 22,550,561 shares of common stock immediately prior to the completion of this offering (ii) the issuance of 173,827 shares of Series B convertible preferred stock upon the exercise of the outstanding preferred stock warrants subsequent to June 30, 2021, which will convert into 12,686 shares of our common stock upon completion of this offering (iii) the issuance and sale of 3,649 shares of common stock on August 2, 2021 to Elisabet de los Pinos, our CEO, pursuant to an option exercise, with an exercise price of \$5.48 per share (iv) the issuance and sale of 2,190 and 1,459 shares of common stock on October 5, 2021 to a holder of our convertible preferred stock, pursuant to an option exercise, with an exercise price of \$5.75 and \$5.48 per share of common stock, respectively and (v) the filing and effectiveness of our tenth amended and restated certificate of incorporation upon the closing of this offering; and
- on a pro forma as adjusted basis to give effect to (i) the pro forma adjustments described above and (ii) our sale in this offering of 5,400,000 shares of common stock at the initial public offering price of \$14.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table should be read together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Description of Capital Stock,” and the financial statements and related notes appearing elsewhere in this prospectus.

	As of June 30, 2021		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share data) (unaudited)		
Cash and cash equivalents	\$ 92,197	\$ 92,453	\$ 160,081
Redeemable convertible preferred stock (Series A, A-1, A-2, B, C-1, C-2, D-1, D-2, E), \$0.00001 par value, 308,506,707 shares authorized, 308,332,857 shares issued and outstanding, actual; 10,000,000 authorized, and no shares issued and outstanding, pro forma and pro forma as adjusted	\$ 215,304	\$ —	\$ —
Stockholders’ (deficit) equity:			
Common stock, \$0.00001 par value, 470,183,383 shares authorized, 439,068 issued and outstanding, actual; 470,183,383 shares authorized, 23,009,613 issued and outstanding, pro forma; 470,183,383 shares authorized, 28,409,613 shares issued and outstanding, pro forma as adjusted	—	1	1
Additional paid-in capital	8,914	224,544	291,892
Accumulated deficit	(131,665)	(131,665)	(131,665)
Total stockholders’ (deficit) equity	(122,751)	92,880	160,228
Total capitalization	\$ 92,553	\$ 92,880	\$ 160,228

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The actual, pro forma, and pro forma as adjusted information set forth in the table excludes:

- 2,908,580 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2021, at a weighted average exercise price of \$4.66 per share;
- 3,352,166 shares of our common stock reserved for future issuance under our 2021 Plan, which became effective on the date immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, including (i) 994,901 shares of our common stock issuable upon the exercise of stock options to be granted to certain employees, including our named executive officers, (ii) 232,111 shares of common stock issuable upon the vesting of RSUs to be granted to certain employees, including our named executive officers and (iii) 72,000 shares of our common stock issuable upon the exercise of stock options granted to our non-employee directors, in each case granted upon the effectiveness of the registration statement of which this prospectus forms a part and with an exercise price equal to the initial public offering price per share; and
- 335,217 shares of our common stock reserved for future issuance under our ESPP, which became effective on the date immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part.

## DILUTION

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

Our historical net tangible book value (deficit) as of June 30, 2021 was \$(124.3) million, or \$(283.16) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and preferred stock, which are not included within stockholders' equity (deficit). Historical net tangible book value (deficit) per share represents our historical net tangible book value (deficit) divided by the 439,068 shares of our common stock outstanding as of June 30, 2021.

Our pro forma net tangible book value as of June 30, 2021 was \$91.3 million, or \$3.97 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 22,550,561 shares of common stock immediately prior to the completion of this offering, the issuance of 173,827 shares of Series B convertible preferred stock upon the exercise of the outstanding preferred stock warrants subsequent to June 30, 2021, which will convert into 12,686 shares of our common stock upon completion of this offering, the issuance and sale of 3,649 shares of common stock on August 2, 2021 to Elisabet de los Pinos, our CEO, pursuant to an option exercise, with an exercise price of \$5.48 per share and the issuance and sale of 2,190 and 1,459 shares of common stock on October 5, 2021 to a holder of our convertible preferred stock, pursuant to an option exercise, with an exercise price of \$5.75 and \$5.48 per share of common stock, respectively. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of June 30, 2021, after giving effect to the automatic conversion of all outstanding shares of our preferred stock into common stock immediately prior to the completion of this offering.

After giving further effect to our issuance and sale of 5,400,000 shares of our common stock in this offering at the initial public offering price of \$14.00 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 June 30, 2021 would have been \$159.0 million, or \$5.60 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of \$1.63 to existing stockholders and immediate dilution of \$8.40 in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		\$14.00
Historical net tangible book value per share as of June 30, 2021	\$(283.16)	
Pro forma increase in net tangible book value per share as of June 30, 2021	<u>287.13</u>	
Pro forma net tangible book value per share as of June 30, 2021, before giving effect to this offering	3.97	
Increase in pro forma net tangible book value per share attributable to investors purchasing shares in this offering	<u>1.63</u>	
Pro forma as adjusted net tangible book value per share immediately after this offering		<u>5.60</u>
Dilution in pro forma as adjusted net tangible book value per share to new investors purchasing shares in this offering		<u>\$ 8.40</u>



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If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted net tangible book value per share after this offering would be \$5.80 per share, representing an immediate increase in pro forma as adjusted net tangible book value per share of \$1.83 to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of \$8.20 to new investors purchasing common stock in this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If any shares are issued upon exercise of outstanding options or warrants, you will experience further dilution.

The following table summarizes, on the pro forma as adjusted basis described above, the differences between the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid by existing stockholders and by new investors purchasing shares of common stock in this offering. The calculation below is based on the initial public offering price of \$14.00 per share, which before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	23,009,613	81.0%	\$218,548,611	74.3%	\$ 9.50
New investors	5,400,000	19.0%	\$ 75,600,000	25.7%	\$ 14.00
Total	<u>28,409,613</u>	<u>100%</u>	<u>\$294,148,611</u>	<u>100%</u>	<u>\$ 10.35</u>

The table above assumes no exercise of the underwriters' option to purchase 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 78.7% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors participating in the offering would be increased to 21.3% of the total number of shares of our common stock outstanding after this offering.

The number of shares of our common stock to be outstanding after this offering is based on 23,009,613 shares of our common stock outstanding as of June 30, 2021, which assumes the automatic conversion of all of our outstanding preferred stock into 22,550,561 shares of common stock immediately prior to the completion of this offering, the issuance of 173,827 shares of Series B convertible preferred stock upon the exercise of the outstanding preferred stock warrants subsequent to June 30, 2021, which will convert into 12,686 shares of our common stock upon completion of this offering, the issuance and sale of 3,649 shares of common stock on August 2, 2021 to Elisabet de los Pinos, our CEO, pursuant to an option exercise, with an exercise price of \$5.48 per share, the issuance and sale of 2,190 and 1,459 shares of common stock on October 5, 2021 to a holder of our convertible preferred stock, pursuant to an option exercise, with an exercise price of \$5.75 and \$5.48 per share of common stock, respectively and excludes:

- 2,908,580 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2021, at a weighted average exercise price of \$4.66 per share;
- 3,352,166 shares of our common stock reserved for future issuance under our 2021 Plan, which became effective on the date immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, including (i) 994,901 shares of our common stock issuable upon the exercise of stock options to be granted to certain employees, including our named executive officers, (ii) 232,111 shares of common stock issuable upon the vesting of RSUs to be granted to certain employees, including our named executive officers and (iii) 72,000 shares of our common stock issuable upon the exercise of stock options granted to our non-employee directors, in each case granted upon the effectiveness of the registration statement of which this prospectus forms a part and with an exercise price equal to the initial public offering price per share; and

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- 335,217 shares of our common stock reserved for future issuance under our ESPP, which will become effective on the date immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part.

To the extent that outstanding options are exercised or shares are issued under our 2021 Plan, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans, strategies, objectives, expectations and intentions for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by these forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."*

### Overview

We are a clinical-stage biotechnology company leveraging our novel targeted oncology platform to develop a potential new standard of care across multiple cancer indications, with an initial focus on ocular and urologic oncology. Our proprietary platform enables the targeting of a broad range of solid tumors using Virus-Like Particles, or VLPs, that can be conjugated with drugs or loaded with nucleic acids to create Virus-Like Drug Conjugates, or VDCs. Our VDCs are largely agnostic to tumor type and can recognize a surface marker, known as heparin sulfate proteoglycans, or HSPGs, that are specifically modified and broadly expressed on many tumors. We are focusing our initial development of VDCs to treat tumors of high unmet need in ocular and urologic oncology. We are focusing our initial development of VDCs to treat tumors of high unmet need in ocular and urologic oncology. AU-011, our first VDC candidate, is being developed for the first line treatment of primary choroidal melanoma, a rare disease with no drugs approved. We have completed a Phase 1b/2 trial using intravitreal administration that has demonstrated a statistically significant growth rate reduction in patients with prior active growth and high levels of tumor control with visual acuity preservation in a majority of patients, as assessed using clinical endpoints in alignment with feedback from the FDA. These data supported advancement into a Phase 2 dose escalation trial, where we are currently evaluating suprachoroidal, or SC, administration of AU-011. We plan to present six to twelve month safety and efficacy data from this trial in 2022, and, if favorable, initiate a pivotal trial in the second half of 2022. We are also developing AU-011 for additional ocular oncology indications and plan to file an IND in the United States in the second half of 2022 for choroidal metastases. Leveraging our VDCs' broad tumor targeting capabilities, we also plan to initiate a Phase 1a trial in non-muscle invasive bladder cancer, or NMIBC, our first non-ophthalmic solid tumor indication, in the second half of 2022 and present Phase 1a data from this trial in 2023.

We were incorporated as a Delaware corporation in 2009 and our headquarters is located in Cambridge, Massachusetts. Since our inception, we have focused our efforts on identifying and developing potential product candidates, conducting preclinical studies and clinical trials, organizing and staffing our company, business planning, establishing our intellectual property portfolio, raising capital, conducting discovery, research and development activities and providing general and administrative support for these operations. We do not have any product candidates approved for sale and have not generated any revenue to date. We have funded our operations primarily through the sale of convertible preferred stock, common stock, and convertible debt. From inception through June 30, 2021, we have raised an aggregate of approximately \$218.5 million of gross proceeds primarily from private placements of our equity and convertible debt securities as well as through the issuance of our common stock.

We have incurred significant operating losses in every year since our inception in 2009 and have not generated any revenue. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our ability to generate product revenue sufficient to achieve profitability will

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depend on the successful development and commercialization of one or more of our product candidates. Our net losses were \$14.8 million and \$13.7 million for the six months ended June 30, 2021 and 2020, respectively, and \$22.2 million and \$24.2 million for the years ended December 31, 2020 and 2019, respectively. As of June 30, 2021, we had an accumulated deficit of \$131.7 million. In addition, our losses from operations 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 anticipate that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly as we advance the preclinical studies and clinical trials of our product candidates. In addition, we expect to incur additional costs associated with operating as a public company following the completion of this offering. We expect that our expenses and capital requirements will increase substantially if and as we:

- conduct our current and future clinical trials of AU-011;
- progress the preclinical and clinical development of new indications;
- establish our manufacturing capability, including developing our contract development and manufacturing relationships;
- seek to identify and develop additional product candidates;
- seek regulatory approval of our current and future product candidates;
- expand our operational, financial, and management systems and increase personnel, including personnel to support our preclinical and clinical development, manufacturing and commercialization efforts;
- maintain, expand and protect our intellectual property portfolio; and
- incur additional legal, accounting, or other expenses in operating our business, including the additional costs associated with operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain marketing approval for our product candidates. The lengthy process of securing marketing approvals for new drugs requires the expenditure of substantial resources. Any delay or failure to obtain regulatory approvals would materially adversely affect the development efforts of our product candidates and our business overall. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of June 30, 2021, we had cash and cash equivalents of \$92.2 million. We believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “—Liquidity and Capital Resources” below.

### ***Impact of the COVID-19 Pandemic***

The COVID-19 pandemic continues to present substantial public health and economic challenges around the world, and to date has led to the implementation of various responses, including government-imposed quarantines, stay-at-home orders, travel restrictions, mandated business closures and other public health safety measures.

We continue to closely monitor the impact of the COVID-19 pandemic on all aspects of our business, including how it has and will continue to impact our operations and the operations of our suppliers, vendors and business partners, and may take further precautionary and preemptive actions as may be required by federal, state or local authorities. In addition, we have taken steps to minimize the current environment's impact on our business and strategy, including devising contingency plans and securing additional resources from third party service providers. For the safety of our employees and families, we have introduced enhanced safety measures for scientists to be present in our labs and increased the use of third party service providers for the conduct of certain experiments and studies for research programs. To date, we've only encountered minor delays in our manufacturing process due to a supply chain constraint with one of our vendors.

Beyond the impact on our pipeline, the extent to which COVID-19 ultimately impacts our business, results of operations and financial condition will depend on future developments, which remain highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the emergence of new variants, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions taken to contain COVID-19 or treat its impact, including vaccination campaigns, among others. If we or any of the third parties with whom we engage, however, were to experience any additional shutdowns or other prolonged business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially or negatively affected, which could have a material adverse impact on our business, results of operations and financial condition. Although to date, our business has not been materially impacted by COVID-19, it is possible that our clinical development timelines could be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition and results of operations. See "Risk Factors" for a discussion of the potential adverse impact of the COVID-19 pandemic on our business, financial condition and results of operations.

### **Components of Our Results of Operations**

#### ***Revenue***

Since inception, we have not generated any revenue and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for one or more of our product candidates are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements. We cannot predict if, and when, or to what extent, we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

#### ***Operating Expenses***

##### *Research and Development Expenses*

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our AU-011 program, and include:

- employee-related expenses, including salaries, related-benefits and stock-based compensation expense for employees engaged in research and development functions;
- fees paid to consultants for services directly related to our product development and regulatory efforts;

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- expenses associated with conducting preclinical studies performed by ourselves, outside vendors or academic collaborators;
- expenses incurred under agreements with contract research organizations, or CROs, as well as consultants that conduct and provide supplies for our preclinical studies and clinical trials;
- the cost of manufacturing AU-011, including the potential cost of CMOs that manufacture product for use in our preclinical studies and clinical trials and perform analytical testing, scale-up and other services in connection with our development activities;
- costs associated with preclinical activities and development activities;
- costs associated with our intellectual property portfolio;
- costs related to compliance with regulatory requirements; and
- allocated expenses for utilities and other facility-related costs.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid or accrued research and development expenses. We allocate our direct external research and development costs across the entire AU-011 program. Preclinical expenses consist of external research and development costs associated with activities to support our current and future clinical programs, but are not allocated by specific indications due to the overlap of the potential benefit of those efforts across the entire AU-011 program.

Research and development activities are central to our business. We expect that our research and development expenses will increase for the foreseeable future as we continue clinical development for AU-011 and continue to discover and develop additional product candidates. If any of our product candidates enter into later stages of clinical development, they will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

### *General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive and finance functions. General and administrative expenses also include professional fees for legal, accounting, auditing, tax and consulting services; travel expenses; and facility-related expenses, which include allocated expenses for rent and maintenance of facilities and other operating costs not included in research and development.

We expect that our general and administrative expenses will increase in the near-term as we continue to build a team to support our administrative, accounting and finance, communications, legal and business development efforts. Following this offering, we expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax compliance services; director and officer insurance costs; and investor and public relations costs.

### *Other Income (Expense)*

Our other income (expense) consists of changes in the fair value of our warrant liability and derivative, gain/loss on disposal of fixed assets, interest expense on outstanding debt, and interest income on our invested cash balances.

### *Income Taxes*

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in any year or for our earned research and development tax credits, due to the uncertainty of realizing a benefit from those items. As of December 31, 2020, we had federal and state gross operating loss carryforwards of \$106.1 million and \$89.3 million, respectively, which may be used to offset future taxable income, if any. Federal gross operating loss carryforwards of \$44.2 million

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begin to expire in 2029 and go through 2037 and federal gross operating loss carryforwards of \$61.9 million do not expire. The state gross operating loss carryforwards begin to expire in 2030. As of December 31, 2020, we had federal and state research and development tax credit carryforwards of \$3.8 million and \$1.1 million, respectively, which may be used to offset future income tax liabilities and begin to expire in 2029 and 2027, respectively. Due to the degree of uncertainty related to the ultimate use of the deferred tax assets, we have fully reserved these tax benefits, as the determination of the realization of the deferred tax benefits was not determined to be more likely than not.

### Results of Operations

#### **Comparison of the Six Months Ended June 30, 2021 and 2020**

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2020:

	Six Months Ended June 30,		Change
	2021	2020	
	(in thousands)		
<b>Operating expenses:</b>			
Research and development	\$ 10,817	\$ 11,649	\$ (832)
General and administrative	3,911	2,017	1,894
Total operating expenses	<u>14,728</u>	<u>13,666</u>	<u>1,062</u>
Loss from operations	<u>(14,728)</u>	<u>(13,666)</u>	<u>(1,062)</u>
<b>Other income (expense):</b>			
Change in fair value of warrant liability	1	–	1
Change in fair value of derivative liability	(52)	–	(52)
Interest income (expense), including amortization of discount	3	(2)	5
Loss from disposal of assets	(3)	–	(3)
Total other expense	<u>(51)</u>	<u>(2)</u>	<u>(49)</u>
Net loss and comprehensive loss	<u><u>\$(14,779)</u></u>	<u><u>\$(13,668)</u></u>	<u><u>\$(1,111)</u></u>

#### *Research and Development Expenses*

The following table summarizes our research and development expenses for the six months ended June 30, 2021 and 2020:

	Six Months Ended June 30,		Change
	2021	2020	
	(in thousands)		
<b>Direct research and development expenses:</b>			
Phase 1b/2 IVT Study	\$ 448	\$ 1,411	\$ (963)
SC Dose Escalation Study	947	297	650
Registry Study	96	137	(41)
Manufacturing Development	4,211	4,323	(112)
<b>Unallocated expenses</b>			
Preclinical	270	1,423	(1,153)
Personnel expenses(1)	3,785	3,011	774
Facility related and other	1,060	1,047	13
Total research and development expenses	<u><u>\$10,817</u></u>	<u><u>\$11,649</u></u>	<u><u>\$ (832)</u></u>

(1) Includes stock-based compensation of \$0.1 million for the six months ended June 30, 2021 and 2020.

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Research and development expenses were \$10.8 million for the six months ended June 30, 2021, compared to \$11.6 million for the six months ended June 30, 2020. The decrease of \$0.8 million was primarily due to decreases of \$1.2 million in preclinical expense and \$0.4 million in expenses for the continued development and the advancement of clinical trials, offset by an increase of \$0.8 million in personnel expenses.

### *General and Administrative Expenses*

General and administrative expenses were \$3.9 million for the six months ended June 30, 2021, compared to \$2.0 million for the six months ended June 30, 2020. The increase of \$1.9 million was primarily due to increases in legal and professional fees of \$1.3 million and personnel expenses of \$0.6 million which was primarily due to an increase in stock-based compensation expense.

### **Comparison of the Years Ended December 31, 2020 and 2019**

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

	Year ended December 31,		Change
	2020	2019	
	(in thousands)		
<b>Operating expenses:</b>			
Research and development	\$ 18,042	\$ 19,617	\$(1,575)
General and administrative	4,164	4,523	(359)
Total operating expenses	<u>22,206</u>	<u>24,140</u>	<u>(1,934)</u>
Loss from operations	<u>(22,206)</u>	<u>(24,140)</u>	<u>1,934</u>
<b>Other income (expense):</b>			
Change in fair value of warrant liability	3	(44)	47
Interest expense, including amortization of discount	(3)	(5)	2
Loss from disposal of assets	—	(11)	11
Total other expense	<u>—</u>	<u>(60)</u>	<u>60</u>
Net loss and comprehensive loss	<u>\$ (22,206)</u>	<u>\$ (24,200)</u>	<u>\$ 1,994</u>

### *Research and Development Expenses*

The following table summarizes our research and development expenses for the years ended December 31, 2020 and 2019:

	Year ended December 31,		Change
	2020	2019	
	(in thousands)		
<b>Direct research and development expenses:</b>			
Phase 1b/2 IVT Study	\$ 1,801	\$ 2,595	\$ (794)
SC Dose Escalation Study	1,062	—	1,062
Registry Study	194	129	65
Manufacturing Development	4,965	8,399	(3,434)
<b>Unallocated expenses</b>			
Preclinical	2,211	1,586	625
Personnel expenses(1)	5,736	5,060	676
Facility related and other	<u>2,073</u>	<u>1,848</u>	<u>225</u>
Total research and development expenses	<u>\$18,042</u>	<u>\$19,617</u>	<u>\$(1,575)</u>

(1) Includes stock-based compensation of \$0.2 million for the years ended December 31, 2020 and 2019.



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Research and development expenses were \$18.0 million for the year ended December 31, 2020, compared to \$19.6 million for the year ended December 31, 2019. The decrease of \$1.6 million was primarily due to \$3.4 million decrease in manufacturing development expenses offset by an increase of \$0.3 million in expenses for the continued development and the advancement of clinical trials, \$0.6 million in preclinical expenses, \$0.7 million in personnel expenses, and \$0.2 million in facility and other expenses related to office space.

### *General and Administrative Expenses*

General and administrative expenses were \$4.2 million for the year ended December 31, 2020, compared to \$4.5 million for the year ended December 31, 2019. The decrease of \$0.3 million was primarily due to a decrease in legal and professional fees.

## **Liquidity and Capital Resources**

To date we have funded our operations primarily through the sale of convertible preferred stock, common stock, and convertible debt. Through June 30, 2021, we have raised an aggregate of approximately \$218.5 million of gross proceeds primarily from private placements of our equity and convertible debt securities and warrants, as well as through the issuance of our common stock. As of June 30, 2021, we had cash and cash equivalents of \$92.2 million and an accumulated deficit of \$131.7 million. 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. We have not yet commercialized our product candidate for any of its multiple indications, which is in various phases of preclinical and clinical development, depending on the indication, and we do not expect to generate revenue from sales of any products for the foreseeable future, if at all. Since our inception we have incurred losses and negative cash flows from operations and expect these conditions to continue for the foreseeable future.

### **Cash Flows**

The following table summarizes our cash flows for each of the periods presented:

	Six months ended June 30,		Year ended December 31,	
	2021	2020	2020	2019
	(in thousands)		(in thousands)	
Net cash used in operating activities	\$(11,634)	\$(13,952)	\$(24,321)	\$(20,666)
Net cash used in investing activities	(733)	(538)	(771)	(2,221)
Net cash provided by financing activities.	87,233	104	10,036	39,726
Net increase (decrease) in cash, cash equivalents, and restricted cash	<u>\$ 74,866</u>	<u>\$(14,386)</u>	<u>\$(15,056)</u>	<u>\$ 16,839</u>

### *Operating Activities*

During the six months ended June 30, 2021, net cash used in operating activities was \$11.6 million, primarily due to our net loss of \$14.8 million offset by increases in our operating assets and liabilities of \$2.3 million and in non-cash charges of \$0.9 million. Increases in our operating assets and liabilities consisted primarily of a \$1.6 million in accounts payable, \$0.4 million in prepaid expenses and other assets and \$0.3 million in accrued expenses and other liabilities. Our non-cash charges consisted primarily of \$0.5 million in stock-based compensation and \$0.4 million in depreciation expense.

During the six months ended June 30, 2020, net cash used in operating activities was \$14.0 million, primarily due to our net loss of \$13.7 million and a decrease in our operating assets and liabilities of \$1.0 million, partially offset by non-cash charges of \$0.7 million. Decreases in our operating assets and liabilities consisted primarily of \$2.1 million in accrued expenses and other liabilities and \$0.2 million in prepaid expenses and other assets offset by \$1.3 million in accounts payable. Our

non-cash charges consisted primarily of \$0.3 million in stock-based compensation and \$0.4 million in depreciation expense.

During the year ended December 31, 2020, net cash used in operating activities was \$24.3 million, primarily due to our net loss of \$22.2 million and decreases in our operating assets and liabilities of \$3.7 million and partially offset by non-cash charges of \$1.6 million. Decreases in our operating assets and liabilities consisted primarily of \$1.7 million in accounts payable, \$1.8 million in accrued expenses and other liabilities and \$0.2 million in prepaid expenses and other assets. Our non-cash charges consisted primarily of \$0.8 million in stock-based compensation and \$0.8 million in depreciation expense.

During the year ended December 31, 2019, net cash used in operating activities was \$20.7 million, primarily due to our net loss of \$24.2 million partially offset by increases in our operating assets and liabilities of \$2.5 million and non-cash charges of \$1.0 million. Increases in our operating assets and liabilities consisted primarily of a \$1.0 million increase in accounts payable and \$1.6 million increase in accrued expenses and other liabilities partially offset by a decrease of \$0.1 million in prepaid expenses and other assets. Our non-cash charges consisted primarily of \$0.5 million in stock-based compensation and \$0.5 million in depreciation expense.

#### *Investing Activities*

Net cash used in investing activities during the six months ended June 30, 2021 and 2020 was \$0.7 million and \$0.5 million, respectively, and for the years ended December 31, 2020 and 2019 was \$0.8 million and \$2.2 million, respectively, due to purchases of property and equipment.

#### *Financing Activities*

During the six months ended June 30, 2021, net cash provided by financing activities was \$87.2 million from the \$80.2 million net proceeds from the sale of Series E convertible preferred stock, \$7.0 million net proceeds from the sale of Series D-2 convertible preferred stock, and \$0.3 million proceeds from stock options exercises, offset by \$0.3 million of payments made for deferred offering costs.

During the six months ended June 30, 2020, net cash provided by financing activities was \$0.1 million from the \$0.1 million proceeds from stock options exercises.

During the year ended December 31, 2020, net cash provided by financing activities was \$10.0 million from the \$9.9 million net proceeds from the sale of Series D-2 convertible preferred stock and \$0.1 million proceeds from stock options exercises.

During the year ended December 31, 2019, net cash provided by financing activities was \$39.7 million from the net proceeds from the sale of Series D-1 convertible preferred stock.

#### **Funding Requirements**

Our plan of operation is to continue implementing our business strategy, continue research and development of AU-011 and any other product candidates we may acquire or develop and continue to expand our research pipeline and our internal research and development capabilities. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our current and future product candidates. In addition, we expect to incur additional costs associated with operating as a public company following the completion of this offering. 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 terminate our research and development programs or future commercialization efforts. Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs, and results of discovery, preclinical development, and clinical trials for our current and future product candidates;

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- the number of clinical trials required for regulatory approval of our current and future product candidates;
- the costs, timing, and outcome of regulatory review of any of our current and future product candidates;
- the cost of manufacturing clinical and commercial supplies of our current and future product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain, skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payers;
- addressing any potential interruptions or delays resulting from factors related to the COVID-19 pandemic;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products, and technologies.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. As of June 30, 2021, we had cash and cash equivalents of \$92.2 million. Based on our research and development plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations into 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations from the sale of additional equity or debt financings, or other capital which comes in the form of strategic collaborations, licensing, or other arrangements. In the event that additional financing is required, we may not be able to raise it on terms acceptable to us, or at all. If we raise additional funds through the issuance of equity or convertible debt securities, it may result in dilution to our existing stockholders. Debt financing or preferred equity financing, if available, may result in increased fixed payment obligations, and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations.

If we raise funds through strategic collaboration, licensing or other arrangements, we may relinquish significant rights or grant licenses on terms that are not favorable to us. 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. If we are unable to raise additional funds

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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 products or product candidates that we would otherwise prefer to develop and market ourselves.

### **Contractual Obligations and Commitments**

The following table summarizes our contractual obligations and commitments as of December 31, 2020.

	Total	Payments Due by Period			
		Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
Operating lease commitments(1)	\$571	\$ 360	\$211	\$ –	\$ –
Total	\$571	\$ 360	\$211	\$ –	\$ –

(1) Amounts in the table above reflect payments due for our lease of office space in Cambridge, Massachusetts that expires July 2023.

Except as disclosed in the table above, we have no long-term debt or finance leases and no material non-cancelable purchase commitments with service providers, as we have generally contracted on a cancelable, purchase-order basis. We enter into contracts in the normal course of business with equipment and reagent vendors, CROs, CMOs and other third parties for clinical trials, preclinical research studies and testing and manufacturing services. These contracts are cancelable by us upon prior notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. These payments are not included in the preceding table as the amount and timing of such payments are not known.

### **Critical Accounting Policies and Significant Judgments and Estimates**

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

While our significant accounting policies are described in greater detail in Note 2 to our financial statements appearing 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 financial statements.

#### **Research and Development Costs**

We expense all costs in performing research and development activities in the periods in which they are incurred. Research and development expenses include salaries and benefits, stock-based compensation expense, lab supplies and facility costs, as well as fees paid to nonemployees and entities that conduct certain research and development activities on our behalf and expenses incurred in connection with license agreements. Non-refundable advance payments for goods or services that will be used for rendered or future research and development activities are deferred and amortized over the period that the goods are delivered, or the related services are performed, subject to an assessment of recoverability.

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. 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 the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

#### **Stock-Based Compensation**

We account for our stock-based compensation as expense in the statements of operations and comprehensive loss based on the awards' grant date fair values. We account for forfeitures as they occur by reversing any expense recognized for unvested awards.

We estimate the fair value of options granted using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of a public market for our common stock and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to us, including stage of product development and life science industry focus. We use the simplified method as allowed by the Securities and Exchange Commission, or SEC, Staff Accounting Bulletin, or SAB, No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock. The fair value of stock-based payments is recognized as expense over the requisite service period which is generally the vesting period.

#### *Determination of the Fair Value of Common Stock*

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors, with input from management, considering third-party valuations of our common stock as well as our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation through the date of the option grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our common stock valuations were prepared using either an option pricing method, or OPM, or a hybrid method, both of which used market approaches to estimate our enterprise value. The hybrid method is a probability-weighted expected return method, or PWERM, where the equity value in one or more of the scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, 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

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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 of the common stock is then applied to arrive at an indication of value for the common stock. 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 only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. These third-party valuations were performed at various dates, which resulted in valuations of our common stock of \$4.25 per share as of December 6, 2019, \$4.38 per share as of August 25, 2020 and December 31, 2020, \$5.48 per share as of March 15, 2021 and \$9.59 as of August 31, 2021.

In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status and results of preclinical studies for our 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 our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or sale of our company in light of prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the biotechnology industry.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

Following the completion of this offering, the fair value of our common stock will be determined based on the quoted market price of our common stock on the date of option grant.

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### *Options Granted*

The following table sets forth, by grant date, the number of shares subject to options granted from January 1, 2020 through the date of this prospectus, 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:

<u>Grant Date</u>	<u>Number of Common Shares Subject to Options Granted</u>	<u>Exercise Price per Common Share</u>	<u>Estimated Fair Value per Common Share at Grant Date</u>	<u>Estimated per Share Fair Value of Options</u>
March 16, 2020	328,323	\$ 4.25	\$ 4.25	\$ 2.74
September 17, 2020	3,647	\$ 4.38	\$ 4.38	\$ 2.74
December 14, 2020	133,574	\$ 4.38	\$ 4.38	\$ 2.74
February 2, 2021	5,327	\$ 4.38	\$ 4.38	\$ 2.74
March 23, 2021	59,538	\$ 5.48	\$ 5.48	\$ 3.56
May 14, 2021	108,755	\$ 5.48	\$ 5.48	\$ 3.56
June 28, 2021	1,410,234	\$ 5.48	\$ 5.48	\$ 3.56
September 22, 2021	299,626	\$ 9.59	\$ 9.59	\$ 6.17

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

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

### **Recent Accounting Pronouncements**

We early adopted ASU No. 2016-02, Leases (Topic 842) effective January 1, 2021 as disclosed in Note 2 to our financial statements appearing elsewhere in this prospectus. The adoption of ASC 842 resulted in the recognition of operating lease liabilities of \$0.6 million and operating lease right-of-use assets of \$0.5 million and the derecognition of deferred rent liabilities of \$0.02 million on our balance sheet as of January 1, 2021.

A description of recently issued accounting pronouncements not yet adopted that may potentially impact our financial position and results of operations is also disclosed in Note 2 to our financial statements appearing elsewhere in this prospectus.

### **Quantitative and Qualitative Disclosures about Market Risks**

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. As of June 30, 2021, our cash and cash equivalents of \$92.2 million consisted of money market funds that invest in U.S. Treasury obligations and government funds with commercial banks and financial institutions. Our exposure to interest rate sensitivity is impacted by changes in the underlying U.S. bank interest rates but is minimal. We have not entered into investments for trading or speculative purposes.

### **Emerging Growth Company Status**

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits that an “emerging growth company” may take advantage of the extended transition period 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 the extended transition period under the JOBS Act. However, we did early adopt ASU No. 2016-02, Leases (Topic 842) effective January 1, 2021 as disclosed in Note 2 to our financial statements appearing elsewhere in this prospectus. Accordingly, our financial statements may not be comparable to the financial statements of public companies that comply with such new or revised accounting standards. 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).

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We will remain an “emerging growth company” until the earliest of: the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; the date we qualify as a “large accelerated filer,” with at least \$700.0 million of equity securities held by non-affiliates; the issuance, in any three-year period, by us of more than \$1.0 billion in non-convertible debt securities; or the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

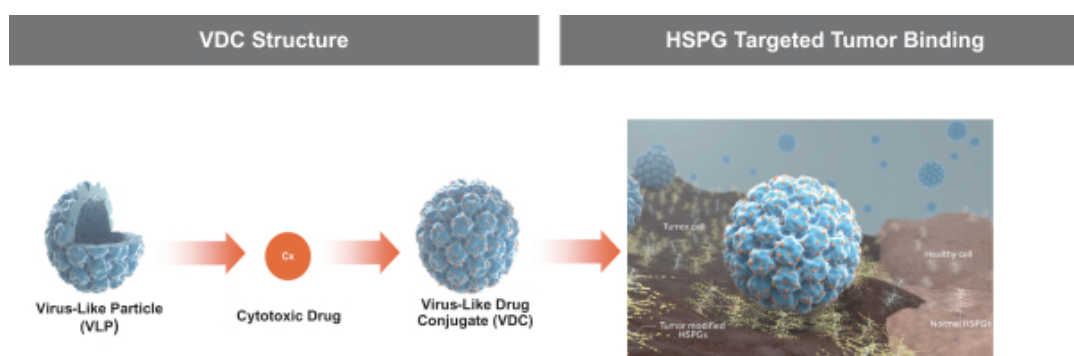


## BUSINESS

### Overview

We are a clinical-stage biotechnology company leveraging our novel targeted oncology platform to develop a potential new standard of care across multiple cancer indications, with an initial focus on ocular and urologic oncology. Our proprietary platform enables the targeting of a broad range of solid tumors using Virus-Like Particles, or VLPs, that can be conjugated with drugs or loaded with nucleic acids to create Virus-Like Drug Conjugates, or VDCs. Our VDCs are largely agnostic to tumor type and can recognize a surface marker, known as heparan sulfate proteoglycans, or HSPGs, that are specifically modified and broadly expressed on many tumors. AU-011, our first VDC candidate, is being developed for the first line treatment of primary choroidal melanoma, a rare disease with no drugs approved. We have completed a Phase 1b/2 trial using intravitreal administration that has demonstrated a statistically significant growth rate reduction in patients with prior active growth and high levels of tumor control with visual acuity preservation in a majority of patients, as assessed using clinical endpoints in alignment with the feedback from U.S. Food and Drug Administration, or the FDA. These data supported advancement into a Phase 2 dose escalation trial, where we are currently evaluating suprachoroidal, or SC, administration of AU-011. We plan to present six to twelve month safety and efficacy data from this trial in 2022 and, if favorable, initiate a pivotal trial in the second half of 2022. We are also developing AU-011 for additional ocular oncology indications and plan to file an IND in the United States in the second half of 2022 for choroidal metastases. Leveraging our VDCs' broad tumor targeting capabilities, we also plan to initiate a Phase 1a trial in non-muscle invasive bladder cancer, or NMIBC, our first non-ophthalmic solid tumor indication, in the second half of 2022 and present Phase 1a data from this trial in 2023.

VDCs are a novel class of drugs with a dual mechanism of action that promotes cancer cell death by both the delivery of the cytotoxic payload to generate acute necrosis and by activating a secondary immune mediated response. VDCs are analogous to ADCs, another technology that employs a targeting moiety and a cytotoxic payload. In contrast to the limited tumor specificity of individual ADCs, the tumor targeting specificity of VDCs is driven by the selective binding of the VLPs to modified HSPGs expressed on the tumor cell membrane. This targeting mechanism enables the delivery of multiple types of cytotoxic payloads directly to a wide range of solid tumors.



**Figure 1. Structure of our VDCs and HSPG Targeted Tumor Binding. The cytotoxic drug payload is covalently bound to the VLP to form the VDC. The capsid proteins that make up the VLP can recognize HSPGs modified by tumor cells and function analogously to the antibody of an ADC.**

We believe that our VDC platform has the potential to serve as a backbone for a broad portfolio of targeted oncology therapeutics and has the following potential key advantages:

1. A single VDC can deliver hundreds of cytotoxic molecules conjugated to its capsid proteins.

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- Based on the ability of VLPs to selectively recognize specifically modified and overexpressed HSPGs present on a large number of tumor types, VDCs have the potential to be used broadly across a wide range of cancers with limited off-target toxicity.
- The VDCs have a high number of HSPG binding sites and this multi-valency permits the strong and selective binding to tumor cells.
- VDCs have a dual mechanism of action, first by acute necrosis of the tumor cells, and subsequently by creating a highly immunogenic milieu that induces an antitumor specific immune response potentially leading to a more robust and durable therapy.

Our goal is to leverage our platform to develop a new class of targeted therapies that bring therapeutic benefit to multiple cancer indications, initially focusing on the field of ocular oncology, a field representing a potential \$1.5 billion market opportunity. Our next area of focus, bladder cancer, is one of the most expensive cancers to treat on a per patient basis, and the global market for bladder cancer is expected to reach \$4.0 billion by 2028 across the United States, EU5 and Japan. To date, we have produced a VDC, AU-011, that we are advancing in multiple indications, as shown in the pipeline below.

Program		Preclinical	Phase 1	Phase 2	Pivotal	Upcoming Milestones
Ocular Oncology	<b>Primary Choroidal Melanoma</b> (Ph1b/2 Intravitreal and Ph2 Suprachoroidal)	[Progress bar spanning Preclinical, Phase 1, and Phase 2]				<ul style="list-style-type: none"> <li>• YE 2021 – Initial Phase 2a safety data</li> <li>• 2022 – Phase 2a safety and efficacy data</li> <li>• 2H 2022 – Initiate Phase 2b (pivotal trial)</li> </ul>
	<b>Choroidal Metastasis</b> (Breast, lung and other cancer metastasis in the eye)	[Progress bar in Preclinical]				<ul style="list-style-type: none"> <li>• 2H 2022 – IND</li> </ul>
	<b>Other Cancers of the Ocular Surface</b> (e.g., SCC, Melanoma)	[Progress bar in Preclinical]				
Other Solid Tumors	<b>Non-Muscle Invasive Bladder Cancer</b>	[Progress bar in Preclinical]				<ul style="list-style-type: none"> <li>• 2H 2022 – Initiate Phase 1a trial</li> <li>• 2023 – Phase 1a data</li> </ul>
	<b>Other HSPG-Expressing Tumors</b> (e.g., Cutaneous Melanoma, HNSCC)	[Progress bar in Preclinical]				

We are initially developing AU-011 for the treatment of primary choroidal melanoma, a vision- and life-threatening ocular cancer for which there are currently no drugs approved. Choroidal melanoma is the most common intraocular cancer in adults, with an incidence of 11,000 patients/year in the United States and Europe. It is estimated that 96% of patients are diagnosed early without clinical evidence of metastatic disease. However, despite the current treatments with radiotherapy the long-term prognosis is poor with death occurring in more than 50% of cases and irreversible vision loss within 5 to 10 years in approximately 70% of cases. We intend to develop AU-011 as a first line therapy to treat early-stage disease which includes small melanomas and indeterminate lesions representing approximately 9,000 patients/year in the United States and Europe. AU-011 has been granted Orphan Drug designation for treatment of uveal melanoma and Fast Track designations for the treatment of choroidal melanoma by the FDA.

AU-011 consists of an HPV-derived VLP conjugated to hundreds of infrared laser-activated molecules. The VDC is designed in a way that prevents the conjugation from interfering with tumor binding enabling its selectivity to specifically modified HSPGs on tumor cells but not to normal cells. Laser activation of AU-011 is designed to result in precise tumor cell killing with minimal damage to surrounding healthy tissues. In the absence of AU-011 activation or binding to the tumor cell membrane, there is no cytotoxic effect. Multiple laser treatments, following a single dose of AU-011, increase antitumor activity because of the reoxygenation of the tumor and the photostability of AU-011. Finally, acute necrosis triggers immunogenic cell death leading to the generation of an adaptive, long-term antitumor immune response.

In our completed Phase 1b/2 trial, AU-011, administered by intravitreal injection, was well-tolerated and demonstrated high levels of local tumor control while preserving vision at twelve months in patients that had prior active tumor growth. The therapeutic regimen of AU-011 achieved tumor shrinkage or a

near-zero growth rate in the majority of patients and was associated with preservation of visual acuity in 71% of patients at twelve months. We are currently conducting a Phase 2 dose escalation trial of AU-011 with SC administration. We intend to initiate the first pivotal trial in 2022. Because our mechanism of action preserves key ocular structures, we also intend to develop AU-011 for additional ocular oncology indications, beginning with choroidal metastases.

In addition, we are developing AU-011 for the treatment of NMIBC. Bladder cancer is the most common malignancy involving the urinary system and is the eighth most common cause of cancer death in men in the United States. While metastatic bladder cancer has several approved therapies, there are very limited options for the treatment of NMIBC. We are planning to initiate clinical development of AU-011 with intramural administration, a novel route of administration, for the treatment of patients with intermediate and high-risk bladder cancer lesions. This novel route of administration is intended to place high levels of the drug at the base of the tumor where laser activation of AU-011 can cause necrosis and prevent residual tumor cells from further growth and recurrence. We have generated preclinical *in vivo* data that supports that our dual mechanism of action can lead to cytotoxicity and long-term antitumor immunity which may further reduce the risk of metastases. We believe this immune response can play an even larger role in bladder cancer, given that bladder cancer has a well-documented response to immune activation. We are conducting IND-enabling studies with AU-011 and intend to begin clinical trials in the second half of 2022 and present Phase 1a data from this trial in 2023.

#### **Our team**

Our team consists of biopharmaceutical experts who have extensive experience in the development of drugs in oncology and ophthalmology. Our CEO and founder, Elisabet de los Pinos, PhD, MBA, was previously part of the marketing team that led the European commercialization of Alimta® for the treatment of lung cancer at Eli Lilly. Cadmus Rich, MD, MBA, CPE, our Chief Medical Officer, a board-certified ophthalmologist, has extensive experience in leading ophthalmology research and development at companies including Inotek, IQVIA and Alcon/Novartis. He has led or participated in over 75 development programs including the submission and approval over ten devices and pharmaceutical products in the United States, Europe, China, Japan and Latin America. Julie Feder, our CFO, previously served as CFO at Verastem Oncology, the Clinton Health Access Initiative and was instrumental in the integration of Genzyme and Sanofi. Mark De Rosch, PhD, our COO, was previously the Chief Regulatory Officer at Epizyme during which time Epizyme received FDA accelerated approval of its first product in two oncology indications. Dr. De Rosch also led Regulatory Affairs at Nightstar Therapeutics, a gene therapy company developing treatments for inherited retinal diseases prior to Nightstar's acquisition by Biogen in 2019. Christopher Primiano, our CBO, led multiple strategic transactions during his prior tenure as CBO and General Counsel at Karyopharm Therapeutics, Inc., a commercial oncology company. The Chairman of our Board of Directors is David Johnson, a biopharmaceutical business leader with more than 25 years of experience in drug development and the former Chief Executive Officer at VelosBio Inc., a clinical-stage oncology company developing novel ADCs and bispecific antibodies that was acquired by Merck in 2020 for \$2.75 billion. Prior to founding VelosBio Inc. he was the Chief Executive Officer at Acerta Pharma B.V. leading to its acquisition by AstraZeneca plc for \$7 billion.

#### **Our Strategy**

Our goal is to leverage our proprietary platform to develop a new class of targeted therapies that deliver meaningful therapeutic benefit to a range of cancer indications with high unmet need in which we believe we can establish a new standard of care. The key elements of our strategy include:

- **Advance AU-011 through late-stage clinical development and, if approved, commercialization for the first line treatment of primary choroidal melanoma.** In our

Phase 1b/2 trial for AU-011 using intravitreal administration, we observed in patients that had prior active tumor growth high levels of local tumor control while preserving vision at twelve months. We are currently evaluating SC administration of AU-011 in a Phase 2 trial in patients with choroidal melanoma and we plan to present the six to 12 month safety and efficacy data from this trial in 2022. We believe SC administration will increase tumor exposure to the drug while reducing exposure in the vitreous. If the Phase 2a portion of this trial is successful, we expect to initiate the Phase 2b randomized portion of this pivotal trial in 2022. We have received orphan drug designation for treatment of uveal melanoma and fast track designation from the FDA for the treatment of choroidal melanoma and have aligned with FDA and EMA on the design and endpoints of this trial. If approved, this would represent the first therapy for primary choroidal melanoma as a first line treatment option, reserving radiotherapy for a second line treatment option. If approved, we intend to independently commercialize AU-011 in ocular cancers using a limited sales force to target the approximately 50 ocular oncologists in the United States and approximately 50 in Europe, who are a focused call point that treat most patients.

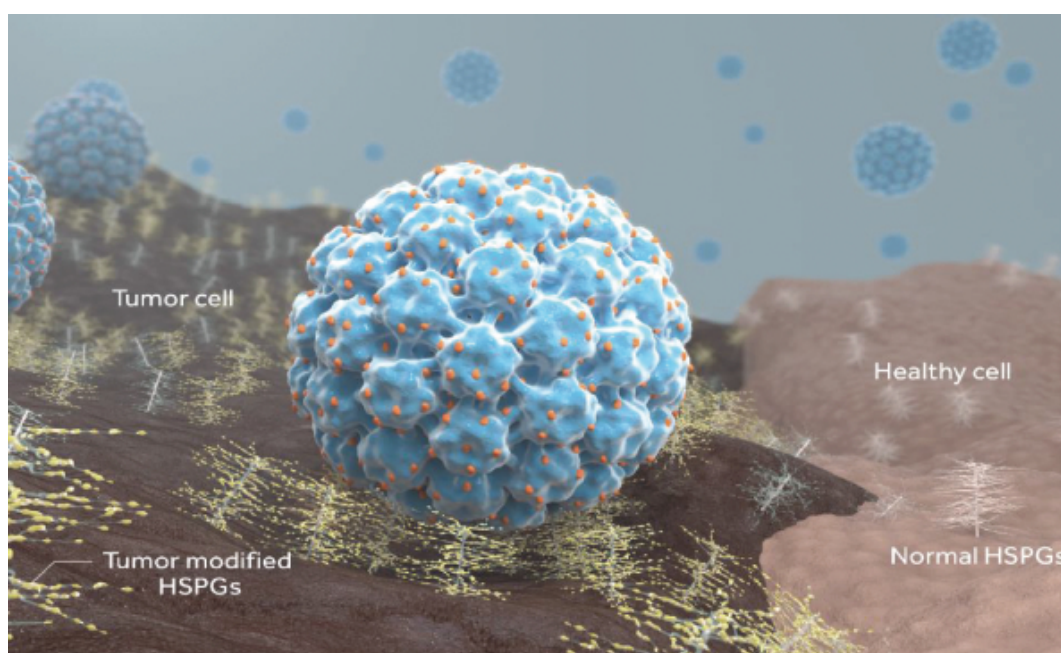
- **Continue developing AU-011 for additional ocular oncology indications, starting with choroidal metastases.** We intend to be at the forefront of ocular oncology innovation and believe we can apply our mechanism of action for AU-011, which has the potential to treat tumors while preserving key ocular structures, to multiple other ocular oncology indications. Beyond small primary choroidal melanoma, we intend to develop AU-011 in multiple other ocular oncology indications, starting with choroidal metastases. We plan to file an IND with the FDA in the second half of 2022 for choroidal metastases. In addition, we plan to develop AU-011 for tumors of the ocular surface, including both melanomas and squamous cell carcinomas. Every year, approximately 4,500 patients are diagnosed with cancers of ocular surface. We believe that we can leverage the sales force infrastructure we intend to build for primary choroidal melanoma for these additional ocular oncology indications.
- **Pursue development of AU-011 for our first non-ophthalmic solid tumor indication in NMIBC.** Our novel approach has the potential benefit of treating early-stage solid tumors, particularly NMIBC, while generating long-term antitumor immunity to prevent metastasis. We believe that local administration into the bladder, and the ability to use a focused laser to activate AU-011, provides the opportunity to apply our technology platform to this area of high unmet medical need. Bladder cancer represents an attractive indication given its sensitivity to immune response and high unmet medical need. AU-011's pro-immunogenic mechanism of action has shown robust activity in preclinical models as a single agent and synergy with checkpoint inhibitors in this indication. Our preclinical data supports initiation of a Phase 1a clinical trial, which we expect to begin in the second half of 2022, subject to FDA acceptance of our IND, with plans to present Phase 1a data from this trial in 2023.
- **Broaden the application of our proprietary technology platform to expand our pipeline of product candidates.** Due to the expression of specifically modified HSPGs across a wide range of solid tumors, we plan to evaluate our technology platform in other oncology indications. We also plan to expand the use of our proprietary technology platform by continuing to explore the potential to deliver other therapeutic agents, including nucleic acid therapies and non-light activated molecules, to broadly treat solid tumors.
- **Evaluate and selectively enter into strategic collaborations to maximize the potential of our pipeline and accelerate the development of our programs.** While we continue to retain worldwide rights to AU-011, we may opportunistically evaluate and enter into strategic collaborations around AU-011 or future product candidates, geographies, or disease areas. We believe our technology platform has the potential to enable the development of a broad scope of product candidates that reaches beyond AU-011. By selectively entering into collaborations, we believe our potential to expand and accelerate the development of our programs and maximize worldwide commercial potential may be enhanced.

### Targeting a broad range of solid tumors with our proprietary technology platform

Our technology platform represents a novel approach of targeting a broad range of solid tumors using VLPs that can be loaded or conjugated with drugs creating a new class of targeted therapies. Our VDCs are analogous to ADCs, another technology that employs a targeting moiety and a payload. ADCs typically utilize a monoclonal antibody to traffic a cytotoxic payload preferentially to tumor cells. There are currently 11 FDA-approved ADCs, six of which have gained regulatory approval since 2019. The class achieved approximately \$4 billion in sales in 2020 and is expected to garner over \$27 billion in sales in 2026.

Despite the successful adoption of this modality, there remains room for improvement. Key challenges related to ADCs include the limited number of payloads that can be conjugated onto the ADC along with toxicities that have been reported. Only two to five toxin drug conjugate molecules per antibody can be delivered, potentially reducing potency, which can necessitate higher doses of toxic drug to be delivered. These higher doses and the expression of ADC target receptors on healthy tissue can lead to systemic toxicity. We believe our VDCs can expand upon the foundation built by ADCs, given VDCs are endowed with specific attributes designed to overcome the shortcomings of ADCs.

The key finding that launched our technology development efforts was the observation that human papilloma virus, or HPV, binds to specifically modified HSPGs on the tumor cell membrane. HSPGs are a large family of molecules found in the extracellular matrix and on the membranes of cells. Tumors specifically modify HSPGs with key sulfation modifications that provide high binding specificity to a number of ligands. Tumor modified HSPGs regulate many aspects of tumor progression, including proliferation, invasion, angiogenesis and metastases. Our scientific founder, John Schiller, PhD, and his colleagues at the National Institutes of Health, or NIH, identified that these specific modifications enable HSPG-selective binding of HPV on tumor cells, as illustrated below.

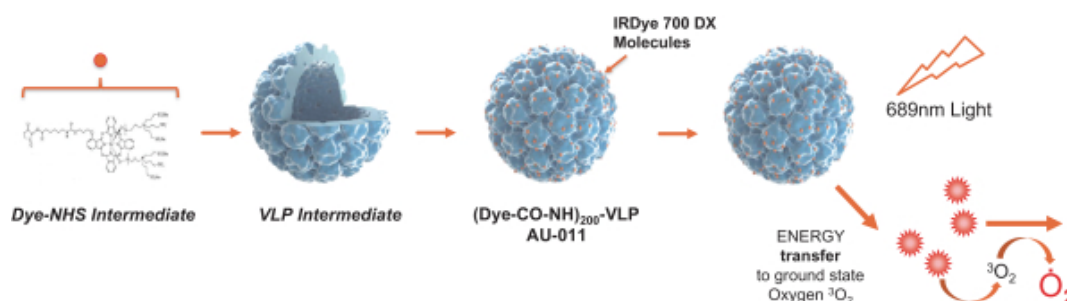


**Figure 2. VDCs bind to specifically modified HSPGs on the tumor cell surface with multivalent binding and do not bind to normal healthy cells.**

This NIH team discovered that HSPG-selective binding of HPV was determined by the properties of the proteins that make up the viral capsid, or shell, not by the nucleic acids contained within the shell. Dr. Schiller pioneered the development of VLPs into a highly effective HPV vaccine to prevent cancer, work for which he received the Lasker-DeBakey Clinical Medical Research Award. He discovered that these capsid proteins could be recombinantly manufactured and could self-assemble into empty VLPs without any viral genome. Our technology platform is based on variants of these VLPs that were further engineered to reduce cross-reactivity with pre-existing immunity against HPV, enabling the use of VLPs as oncology therapeutics. This platform leverages the tumor-specific targeting mechanism of HPV VLPs to enable their use to deliver cytotoxic payloads directly to a wide range of solid tumors. VLPs have also demonstrated the ability to deliver nucleic acids, potentially expanding our platform on which to base a novel class of oncology therapies.

Our first VDC, AU-011, covalently conjugates approximately 200 molecules of an infrared light-activated molecule, IRDye® 700DX, to the VLP in a way that is designed not to interfere with tumor binding. IRDye® 700DX, a photosensitizer that received conditional marketing approval in Japan as part of an ADC (Akalux), is activated with near infrared light at 689 nm. AU-011 is activated using a laser produced by a third party which has the same wavelength and intensity as that used in the activation of Visudyne®, an approved therapy for the treatment of complications due to exudative age-related macular degeneration. The main difference between current commercial ophthalmic lasers and the laser used for AU-011 is in the software. Current commercial ophthalmic lasers use a single pulse of light, whereas the laser used with AU-011 provides multiple pulses of light to ensure complete coverage of the tumor. We utilize lasers that we purchased from two separate manufacturers.

AU-011 given by SC administration uses the SCS Microinjector® developed by Clearside Biomedical, Inc., or Clearside, which requires minimal training for the clinicians to use properly, and the procedure is performed in the ophthalmologist's office. The SCS Microinjector® was developed by Clearside to support the administration of their ophthalmic steroid product XIPERETM (triamcinolone acetonide suprachoroidal injectable suspension). We have an exclusive license with Clearside for use of the SCS Microinjector® for ocular oncology indications. Assuming marketing approval of AU-011, we plan to provide the SCS Microinjector® to the ocular oncologist's office along with the AU-011 drug product.



**Figure 3. VDC structure and mechanism of light activation with generation of singlet oxygen.**

Activation of the dye leads to light absorption, excitation of electrons and generation of highly reactive singlet oxygen, which has little or no opportunity to diffuse away from where it is generated due to its half-life in aqueous solution of less than 4 microseconds. As a result of the VDC's targeted binding to the tumor cell, the generation of singlet oxygen in very close proximity to the tumor cell membrane causes a physical disruption of the cell membrane that leads to acute cellular necrosis. Physical ablation of the tumor cell membrane is an especially potent modality for cancer cell killing because, unlike many other

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therapeutic mechanisms, there is minimal potential to trigger specific mutations, pathway alterations or other compensatory mechanisms or for tumors to develop resistance. In addition, this mode of cell killing leads to acute necrosis, as opposed to apoptosis. Necrosis is highly pro-immunogenic since the contents of the cell, including tumor-specific neoantigens and damage-associated molecular patterns, or DAMPs, are exposed to the immune system triggering the activation of both the innate and adaptive immune systems and generating long-term antitumor activity.

We believe that our technology platform has the potential to serve as a backbone for a broad portfolio of therapeutics. There are four key potential advantages of VDCs compared to ADCs:

1. A single VDC can deliver hundreds of cytotoxic molecules conjugated to its capsid proteins.
2. The VDCs have a high number of HSPG binding sites and, it is this multi-valency that permits the strong binding of the VDCs with tumor cells.
3. Based on the ability of VLPs to selectively recognize specifically modified and overexpressed HSPGs present on a large number of tumor types, VDCs have the potential to be used broadly across a wide range of cancers with limited off-target toxicity.
4. Tumor treatment with VDCs results in a dual mechanism of action, both directly with acute necrosis of the tumor cells, and indirectly by creating a highly immunogenic milieu inducing an antitumor specific immune response leading to a more robust and durable therapy.

## Our pipeline

Our wholly owned product pipeline, which is based on our first VDC, AU-011, is summarized below.

Program		Preclinical	Phase 1	Phase 2	Pivotal	Upcoming Milestones
Ocular Oncology	<b>Primary Choroidal Melanoma</b> (Ph1b/2 Intravitreal and Ph2 Suprachoroidal)	[Progress bar spanning Preclinical, Phase 1, and Phase 2]				<ul style="list-style-type: none"> <li>• YE 2021 – Initial Phase 2a safety data</li> <li>• 2022 – Phase 2a safety and efficacy data</li> <li>• 2H 2022 – Initiate Phase 2b (pivotal trial)</li> </ul>
	<b>Choroidal Metastasis</b> (Breast, lung and other cancer metastases in the eye)	[Progress bar spanning Preclinical and Phase 1]				<ul style="list-style-type: none"> <li>• 2H 2022 – IND</li> </ul>
	<b>Other Cancers of the Ocular Surface</b> (e.g., SCC, Melanoma)	[Progress bar spanning Preclinical]				
Other Solid Tumors	<b>Non-Muscle Invasive Bladder Cancer</b>	[Progress bar spanning Preclinical and Phase 1]				<ul style="list-style-type: none"> <li>• 2H 2022 – Initiate Phase 1a trial</li> <li>• 2023 – Phase 1a data</li> </ul>
	<b>Other HSPG-Expressing Tumors</b> (e.g., Cutaneous Melanoma, HNSCC)	[Progress bar spanning Preclinical]				

## AU-011 for the treatment of ocular cancers

AU-011, our first VDC candidate, is a VLP conjugated with approximately 200 molecules of a novel laser activated cytotoxin, IRDye® 700DX, and is being developed for the first-line treatment of primary choroidal melanoma. AU-011 is designed to be administered into the eye by intravitreal or SC administration, and then activated by an ophthalmic laser. We have completed a Phase 1b/2 trial using intravitreal administration that has demonstrated a statistically significant growth rate reduction in patients with active growth and high levels of tumor control with visual acuity preservation in a majority of patients. We are currently evaluating SC administration of AU-011 in a Phase 2 trial in patients with choroidal melanoma. We plan to present six to twelve month safety and efficacy data from this trial in 2022. If favorable, we expect to initiate the Phase 2b randomized portion of this pivotal trial using the optimal dose and route of administration in the second half of 2022. Beyond primary choroidal melanoma, we are developing AU-011 in multiple ocular oncology indications, starting with choroidal metastases.

### ***Choroidal melanoma overview***

Choroidal melanoma is the most common intraocular cancer in adults, with an incidence of 11,000 patients/year in the United States and Europe. This comprises approximately 90% of all cases of uveal melanoma, consisting of melanomas in the choroid, ciliary body and iris, which are collectively referred to as the uvea. It is estimated that 96% of patients are diagnosed early without clinical evidence of metastatic disease. There are approximately 2,000 new cases treated each year in the United States and 1,600 new cases treated each year in Europe. However, despite the current treatments with radiotherapy, the long-term prognosis is poor with death occurring in more than 50% cases and irreversible vision loss within 5 to 10 years in approximately 70% of cases. We intend to develop AU-011 as a first line therapy to treat early-stage disease which includes small melanomas and indeterminate lesions representing approximately 9,000 patients in the United States and Europe. Most cases are found in adults with a median age of 55, light eye color and fair skin. It is often discovered in patients who are asymptomatic, although some patients report decreased vision or non-specific visual symptoms such as flashes, floaters, blurry or distorted vision or visual field defects. Most choroidal melanomas result from transformation of a benign choroidal nevus. In early stage lesions, most of the tumor is composed of benign nevi cells with a small cluster of malignant melanoma cells. Benign choroidal nevi are found in approximately 5% of adults in the United States 40 years or older. There are 3,900 patients every year in the United States that are diagnosed with indeterminate melanocytic lesions that have risk factors and that are referred to the ocular oncologist.

There has been great progress in the early diagnosis of choroidal melanoma in the last 30 years with the identification of risk factors that can differentiate benign choroidal nevi from high-risk melanocytic lesions. These risk factors are diagnosed by the ocular oncologists with an ophthalmic exam and specialized imaging equipment that can determine the size of the lesion, pigmentation, the presence of subretinal fluid, active growth in tumor height and diameter, decreased vision, visual symptoms and ultrasound hollowness. Early melanocytic lesions are typically managed by a conservative “watch and wait” period to confirm the change in risk factors or early signs of growth which confirms malignant transformation before treatment with radiotherapy is recommended. We believe that the availability of a safe and effective therapy has the potential to change the treatment paradigm for these early tumors, reducing the risk of development of metastatic disease. There are currently no FDA approved therapies for primary choroidal melanoma.

Choroidal melanoma is of grave concern for patients based on this potential to develop into metastatic disease with a high rate of mortality. At the time of diagnosis, less than 4% of patients with choroidal melanoma have detectable metastatic disease. However, the proportion of patients who develop metastases increases with the size of the primary tumor and patient age. A tumor that is less than 2 mm thick has a 10% chance of being associated with metastatic disease, but that risk increases to 24% with tumors that are 4.5 mm and greater than 50% chance in tumors greater than 8 mm.

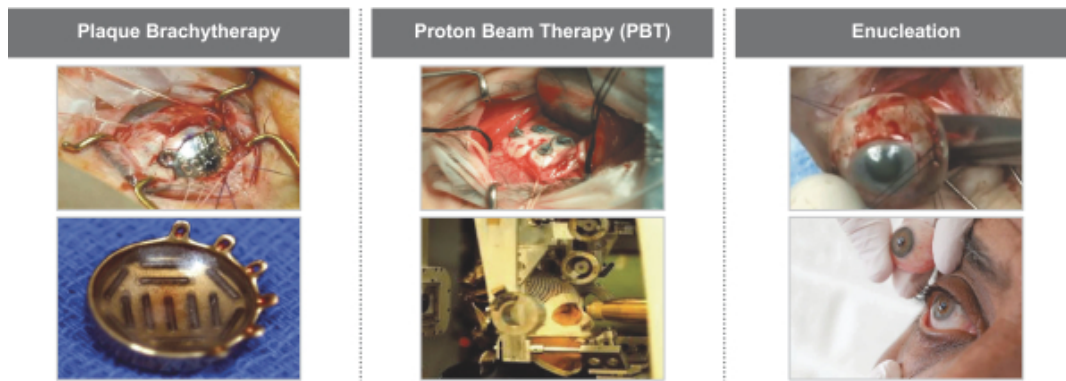
The risk of lethal metastatic disease also increases with lesion size. Patients face an 80% mortality risk within one year of diagnosis and a 92% mortality risk within two years. Overall survival for patients with metastatic disease is less than a year and there are no FDA-approved drugs to treat metastatic disease. This drives a strong desire to treat patients with early stage disease, comprised of patients with either small melanoma or high-risk indeterminate lesions, with the hope of preventing metastasis and ultimately increasing the probability of saving the patients' lives.

Our goal is to develop AU-011 as a first line treatment option that can enable early treatment intervention of primary choroidal melanoma while preserving vision and reserving radiotherapy for a second line treatment option. Earlier diagnosis and early treatment intervention of lesions in the eye before the onset of metastatic disease may dramatically change outcomes for patients.



*Current treatment options for choroidal melanoma*

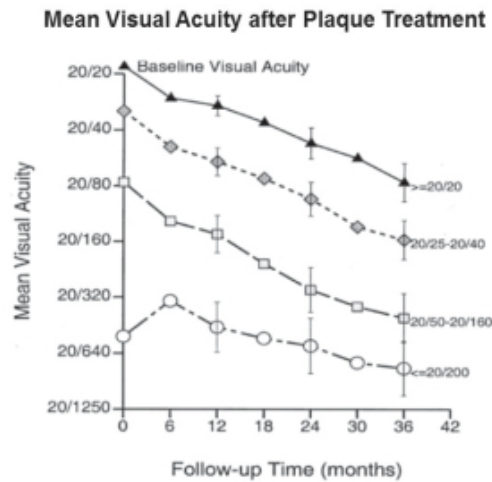
There are no FDA-approved therapies for choroidal melanoma. There are three primary treatments that are routinely used for local control of choroidal melanoma: plaque brachytherapy; proton beam irradiation; and enucleation, or removal of the affected eye, each of which represent invasive surgical procedures.



**Figure 4. Three primary treatments for choroidal melanoma.**

Plaque brachytherapy has been a standard treatment to treat intraocular tumors for decades. In this procedure, a metal carrier, typically a thin sheet of gold, is coated on the inner surface with radioactive seeds, normally iodine-125, or  $^{125}\text{I}$ , and surgically placed over the tumor where it can irradiate the tumor for up to seven days, after which a second surgery is performed to remove the plaque. Patients are followed every three to six months to observe tumor response and to treat radiation related comorbidities. Plaque brachytherapy is an operating room procedure that requires the ocular oncologist to coordinate with the radiation oncologist and medical physicist to identify the precise location and dimensions of the lesion to be treated, calculation of the proper radiation dose to be delivered, and the design of the plaque.

Plaque brachytherapy has demonstrated local tumor control in approximately 85% of cases. However, there is no evidence that plaque brachytherapy is effective in reducing the rate of development of metastasis, especially because metastasis may have occurred before the primary tumor was treated. Because radiotherapy lacks tumor tissue specificity, plaque brachytherapy is associated with the irreversible loss of vision over time in many patients. This loss of vision represents a negative outcome related to damage caused by the radiotherapy to key ocular structures and in particular to the retinal blood vessels. A large, randomized, long-term follow-up trial, known as COMS, was conducted to investigate the benefit of plaque brachytherapy versus enucleation. In this trial, vision loss was defined as a loss of visual acuity of more than six lines on an eye chart. It was discovered that by one year, 18% of patients, by two years, 34% of patients and by three years, 49% of patients, with medium tumors undergoing plaque brachytherapy had severe vision loss. Additionally, 47% of patients at three years had 20/200 or worse vision, the legal definition of blindness in the United States.



**Figure 5. Visual Acuity declines in patients treated with plaque brachytherapy.**

Other than vision loss, plaque brachytherapy is associated with significant posterior segment complications, like scleral necrosis, and potential disfigurement due to complications of the surgery, as well as other adverse events.

A second method of treating choroidal melanoma with similar efficacy as plaque brachytherapy is proton beam therapy, which also deploys a form of ionizing radiation that causes DNA damage and cell death by apoptosis both to tumor and healthy cells. In this procedure, patients undergo surgery to place tantalum markers, which are tiny metal rings, to demarcate the edges of the tumor. After the inflammation due to the surgery has diminished, tumors are irradiated once daily, typically for up to seven days. However, the use of proton beam therapy is limited by the availability of very expensive proton therapy centers. There are less than thirty centers that offer proton therapy in the United States.

Since the radiation typically enters the front of the eye, eyelash loss, eyelid damage, corneal damage, dry eye, glaucoma and cataracts are common after treatment with proton beam therapy. Some of these effects occur within weeks of treatment. Like plaque brachytherapy, patients also may suffer from progressive and irreversible vision loss after proton beam therapy.

Enucleation was previously the standard treatment for ocular cancers. Now, enucleation is reserved either for patients whose tumors are too large or too diffuse to be treated with other treatments; or for use after side effects of radioactive treatments occur. Approximately 10% to 15% of patients treated with radiation therapy end up with an enucleation due to local recurrence of their tumor or to the devastating side effects from radiation treatment. Based on the results from the COMS trial, over a period of at least twelve years, there was no survival difference between patients whose tumors were treated with <sup>125</sup>I brachytherapy and those treated with enucleation.

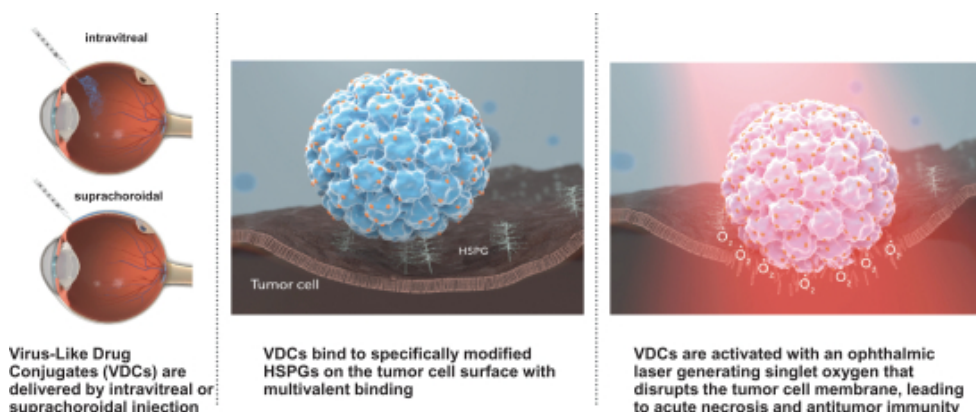
The limited options available to treat patients with choroidal melanoma pose challenges to clinicians and patients. The existing treatments are far from innocuous: all of them are invasive procedures that are associated with irreversible loss of visual acuity and other deleterious side effects. Because choroidal melanoma tends to metastasize early, even with radical treatments such as enucleation, metastatic disease still occurs, which results in a high degree of mortality. We believe that there is an urgent unmet medical need for an effective vision preserving therapy and that the availability of such a therapy may encourage treatment of early stage ocular lesions and increase the awareness of the importance of early diagnosis for this life-threatening disease.

**Our solution AU-011**

AU-011 is a VDC consisting of an HPV-derived VLP and IRDye 700DX, a laser activated cytotoxic payload. Our VLP was created using the capsid proteins of HPV that have been genetically modified to avoid cross-reactivity with pre-existing immunity against the virus and bind with high affinity to specifically modified HSPGs found on the surface of tumors cells, including ocular melanoma cells.

Five observations from our preclinical experiments supported the advancement of AU-011 into clinical development for the treatment of choroidal melanoma:

- AU-011 was shown to selectively bind to HSPGs on human ocular melanoma cells (and other tumor cells) and not to normal cells.
- Infrared light activation of AU-011 using an ophthalmic laser resulted in precise tumor cell killing with minimal damage to surrounding tissues.
- In the absence of light activation or binding to the tumor cell membrane, there was no cytotoxic effect.
- Multiple laser treatments, following a single dose of AU-011, increased antitumor activity because of the reoxygenation of the tumor and the photostability of AU-011.
- Acute necrosis triggered immunogenic cell death, which releases neoantigens and DAMPs, leading to the generation of an adaptive, long-term antitumor immune response.



**Figure 6. AU-011, administered by intraocular injection, binds to tumor cells. Activation using an ophthalmic laser leads to rupture of the tumor cell membrane, acute necrosis and a secondary immune activation leading to long term antitumor immunity.**

Goal of Treatment with AU-011

In ocular oncology, the goal of early stage local treatment is to achieve tumor control—to prevent the tumor from growing further while preserving the delicate ocular structures such as the retina. We believe that treatment early in the disease course can also limit the risk of metastasis for patients. After treatment, if tumors do not have an increase in thickness by ultrasound or an increase in diameter as evaluated with digital photography, it is believed that the malignant cells have been killed, tumor control has been achieved and the treatment is considered successful. Ocular oncologists measure the antitumor activity after plaque brachytherapy by evaluating tumor control as well as systemic disease to detect the presence of metastasis.

Based on preclinical experiments, we believe that early treatment with AU-011 will selectively kill the malignant cells that are localized in the lesion and leave the benign melanocytes and other surrounding cells unaffected. In addition, we believe our treatment is highly pro-immunogenic, meaning

that the necrotic tumor cells would trigger the infiltration of immune cells. The inflammatory process has the potential to transform the lesion into a fibrotic scar, resulting in long-term tumor control and potentially an antitumor response that prevents the onset of metastases.

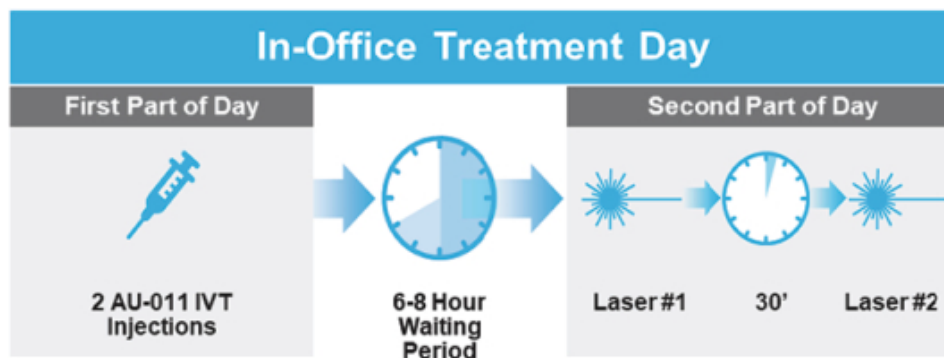


**Figure 7. Goal of treatment with AU-011 is local tumor control with targeted killing of melanoma cells.**

We believe that patients with earlier stage tumors stand to derive the most benefit from AU-011. These tumors are not only the most likely to respond to our therapy but, based on historic data, these patients also have the highest likelihood of not having already developed life-threatening metastatic disease, and as such, AU-011 has the potential to confer the greatest long-term benefit.

*Phase 1b/2 clinical trial design*

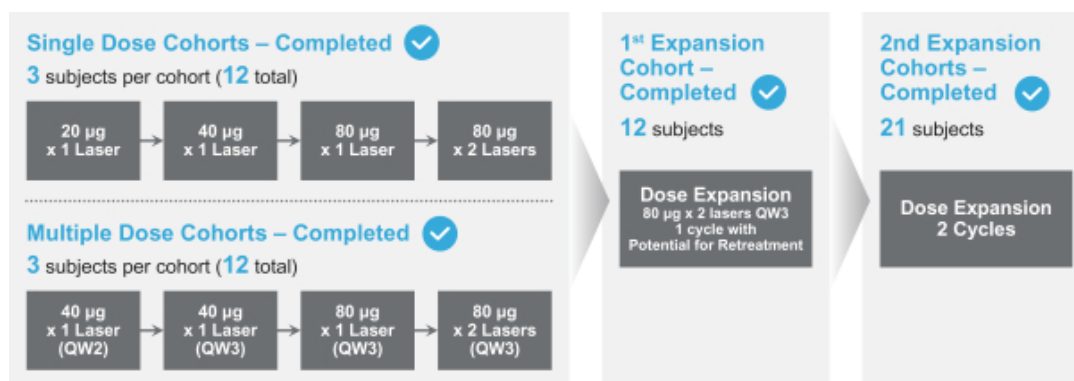
We have completed a Phase 1b/2 clinical trial of AU-011 for the first-line treatment of patients with a clinical diagnosis of choroidal melanoma. AU-011 was administered locally in the eye using two intravitreal injections and then activated with two focused laser treatments approximately six hours after administration and thirty minutes apart per treatment day, as illustrated below. We refer to one cycle of treatment as three treatment days of the course of two weeks (e.g., on days 1, 8 and 15).



**Figure 8. Treatment regimen of AU-011 with intravitreal administration and laser activation in choroidal melanoma.**

Our Phase 1b/2 clinical trial of AU-011 included 57 adult patients with a clinical diagnosis of primary choroidal melanoma, tumor thickness of 0.5 mm - 3.4 mm, a largest basal diameter, or LBD, of

£16 mm with risk factors and/or documented growth. The trial included single and multiple dose escalation cohorts and two dose expansion cohorts. AU-011 was initially administered to patients starting with a single 20 mg dose followed by a single laser treatment, then the dose was increased to 40 mg and then 80 mg, followed in each case by two laser administrations. The dose escalation phase was completed without any dose limiting toxicities or clinically significant adverse events observed. In the first expansion cohort, patients were treated with one cycle of treatment. In the second expansion cohort, a second cycle of treatment three months after the initial cycle was added with the goal of optimizing antitumor activity and preventing tumor recurrence. Patients who failed AU-011 therapy were eligible to be treated with standard of care radiotherapy treatment as determined by the clinical investigator.



**Figure 9. Phase 1b/2 clinical trial design of AU-011 with intravitreal administration in choroidal melanoma.**

Ocular oncologists evaluate tumor control after radiotherapy primarily by ultrasound measurements of the tumor thickness, which are highly accurate to detect submillimeter differences in thickness and detect changes in the tumor diameter with either fundus photography measurements or ultrasound measurements. In our Phase 1b/2 trial, tumor control with AU-011 was evaluated using the same methodology. In addition to tumor control, the growth rate of the tumor was also evaluated before and after treatment in those tumors that had active growth at study entry. By focusing on such active tumors with active growth, we believe we have a greater ability to measure the clinical activity of AU-011 in terms of both reducing the rate of tumor growth needed to see a statistically significant response and positively impacting the tumor control rate while implementing a smaller trial.

Based on communications with the FDA, during our Phase 1b/2 trial, we evaluated the effectiveness of AU-011 in terms of tumor control and visual acuity preservation using the endpoints and thresholds in the table below.

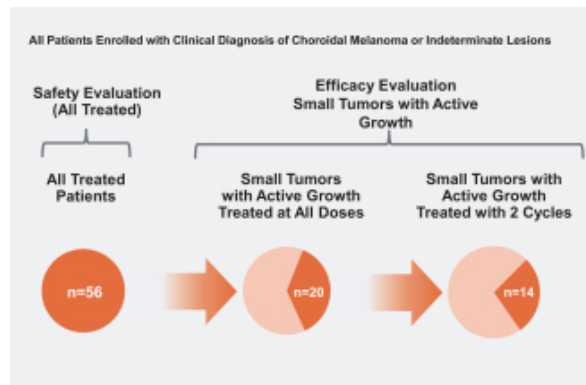
Endpoint Definition	Threshold	Methodology
Tumor Thickness Growth Rate	Tumor thickness growth over 12 months	Ultrasound
Tumor Progression	Growth in Tumor Height >0.5mm and >1.0mm in Largest Basal Diameter*	Ultrasound and Digital Photography
Visual Acuity Loss	Long Term Loss ≥15 letters	ETDRS-BCVA

\* Not judged by the Investigator to be due to inflammation/swelling, hemorrhage or pigmentary changes

**Figure 10. Efficacy endpoints for our clinical trials in choroidal melanoma.**

*Phase 1b/2 demonstrated robust antitumor activity*

A total of 56 patients out of 57 patients enrolled with a clinical diagnosis of choroidal melanoma were treated with AU-011, due to one patient not having met predefined active growth criteria. Tumor growth measurements were obtained by one centralized reading center. Most patients (53 out of 56) had small tumors between 1 mm and 3 mm in height and a diameter less than 10 mm. Twenty patients had small tumors with active growth of 0.3 mm or greater in tumor height within the two years prior to enrollment, a sign that the tumors were actively growing prior to treatment with AU-011. Fourteen of the 20 patients with active growth were treated with two cycles of AU-011, which was the highest dose and most frequent regimen examined in this trial.

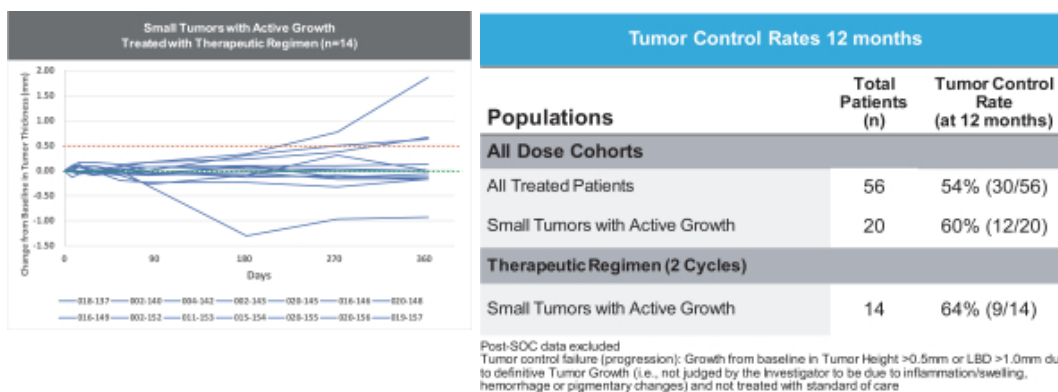


**Figure 11. Patient disposition in the Phase 1b/2 trial.**

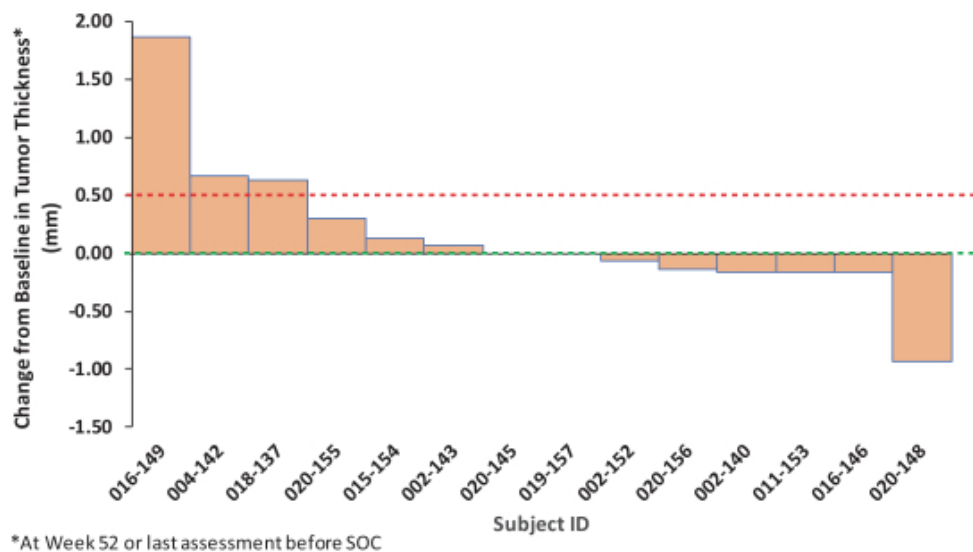
In our Phase 1b/2 trial, the tumor control rate at twelve months across all treatment doses and initial tumor sizes was 54% based on the predefined criteria of tumor control failure as an increase in thickness of greater than 0.5 mm or an increase in diameter of more than 1.0 mm.

During the conduct of our trial, and based on feedback from key opinion leaders and ocular oncology experts, we amended the protocol and statistical analysis plan for the trial to analyze certain subgroups. The key two subgroups were patients with well-documented active growth (n=20) and those with well-documented active growth treated at the highest therapeutic regimen (n=14). The 20 patients with well-documented active growth treated at all doses had a tumor control rate of 60%. The 14 patients with well-documented active growth treated at the highest therapeutic regimen had a tumor control rate of 64%.

Data from the 14 patients with small tumors treated with two cycles of AU-011 showed that nine patients had tumor control, of which six patients had some degree of tumor thickness reduction measured at twelve months. Five patients did not realize tumor control, of which three patients had tumor control failure based on an increase in tumor thickness and LBD, one patient had tumor failure based on an increase in LBD and one patient was treated with radiation therapy early by the investigator before the treatment failure criteria were met.



**Figure 12. Change from baseline in tumor thickness over 12 months and tumor control rates at 12 months.**



**Figure 13. Change in tumor thickness at twelve months or at the last measurement before administration of standard of care for the 14 patients with actively growing tumors treated with two cycles of AU-011.**

When compared to each patient's rate of tumor growth within the prior two years before enrollment, the growth rate after treatment with AU-011 at any dose demonstrated a statistically significant reduction both when assessing patients with active growth in all dose cohorts as well as patients on the therapeutic regimen.

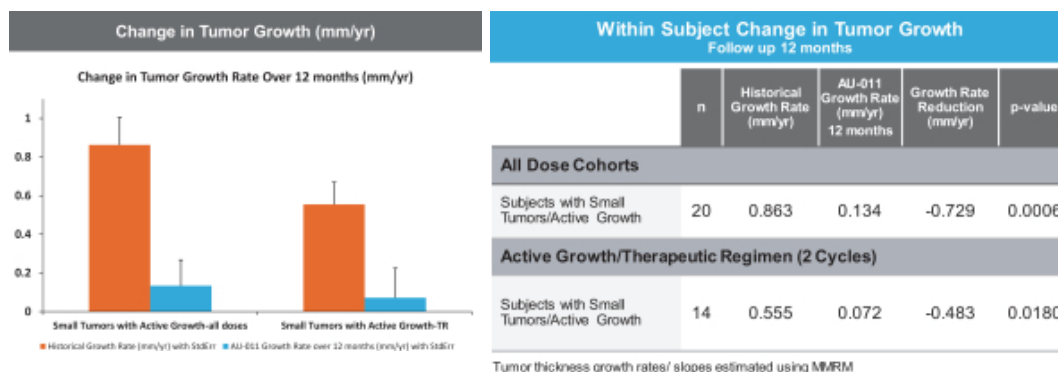


Figure 14. Tumor growth rates in AU-011 treated patients were reduced compared to their growth rates prior to enrollment. The growth rate reduction at 12 months was statistically significant.

Phase 1b/2 demonstrated preservation of visual acuity

We believe that showing preservation of visual acuity will be critical in our application for regulatory approval of AU-011 to show that it can both halt tumor growth and preserve visual acuity. Visual acuity was measured at regular intervals as a key efficacy endpoint. In the Phase 1b/2 trial we defined the loss of visual acuity as the loss of three lines of vision, or 15 letters, using best corrected visual acuity, or BCVA, which the FDA considers a clinically meaningful vision loss. We found moderate loss of visual acuity immediately following treatment, which we believe was associated with short-term reversible adverse events such as ocular inflammation and corneal abrasions. Upon resolution of the short-term adverse events, visual acuity recovered in the majority of patients, and we observed a vision preservation rate of 86% across all 56 treated patients in the trial over the twelve months follow up period and 71% for the 14 patients enrolled with active growth and treated with two cycles of AU-011 therapy.

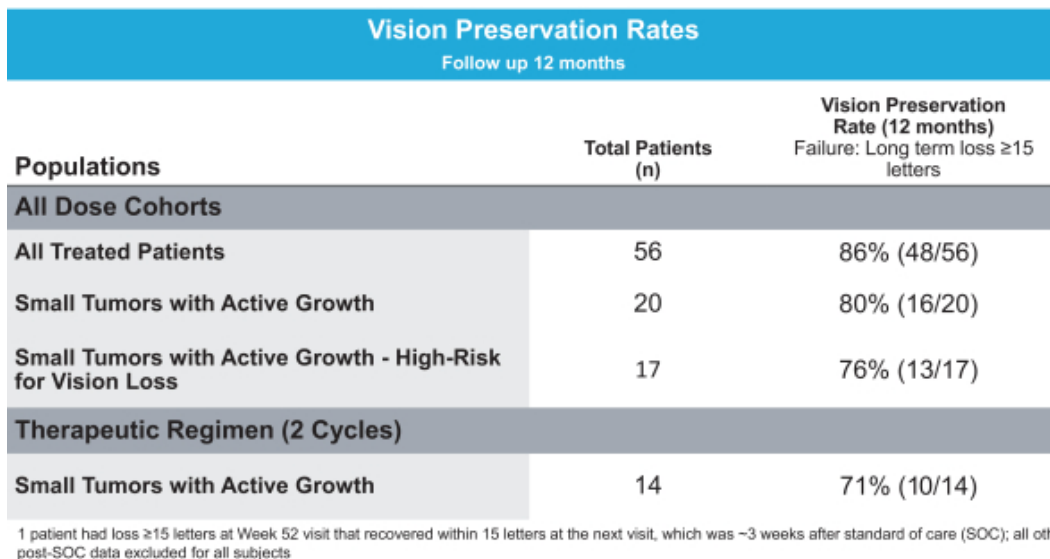


Figure 15. Visual acuity was maintained after treatment with AU-011 in a majority of patients with 12 months follow up.



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Only four out of 14 patients with small tumors with active growth had a long-term loss of more than 15 letters of vision that did not recover back to less than the 15 letters at 12 months. These were related to persistent adverse events, such as pigmentary changes, macular edema or subretinal fluid. Of the four patients that had persistent vision loss, two lost greater than 30 letters and the other two had a loss of 17 and 18 letters which is close to the threshold of 15 letters.

Importantly, 17 of the 20 patients with small tumors with active growth had tumors close to the fovea or optic nerve and were considered high risk for severe vision loss with radiotherapy. In this patient population, the vision preservation rate was 76% (13/17 patients) highlighting a potential important benefit AU-011 may have over the current standard of care.

### Phase 1b/2 safety and tolerability data

Treatment with AU-011 was generally reported to be well-tolerated at all doses including when two cycles of therapy were administered. Adverse events were generally mild or moderate, transient and manageable with standard of care treatments in most patients. Expected AEs of vitreous inflammation, anterior chamber inflammation and increased intraocular pressure were manageable with steroid treatment and ocular antihypertensives.

Intraocular inflammation represented the most common treatment related AE, which was expected given the viral-like component of our drug and the pro-immunogenic mechanism of action. These inflammatory events included anterior chamber inflammation in approximately 71% of patients and posterior inflammation in 91% of patients. Posterior inflammation originated in and around the tumor, suggesting that this inflammation may, at least in part, be related to potential antitumor activity of AU-011. This inflammation was not prophylactically treated, which allowed the immune response to initiate before starting steroid therapy. Cases of anterior inflammation were treated with topical steroid drops, while posterior inflammation was treated with topical, oral, intravitreal or periocular steroids. Approximately 46% of patients also had transient increases in intraocular pressure that were managed with topical anti-hypertensives. One patient had a Grade III vitreous opacity that was removed with surgery.

All Treated Patients (n=56) Key Treatment Related Adverse Events (≥10% Subjects)	Grade I (%)	Grade II (%)	Grade III (%)	Total (%)
Vitreous Inflammation	25.0	58.9*	7.1	91.0
Anterior Chamber Inflammation	37.5	30.4	3.6	71.5
Increase in Intraocular Pressure	21.4	25.0	0	46.4
Peritumoral RPE/ Pigmentary Changes	32.1	5.4	0	37.5
Keratic Precipitates	21.4	1.8	0	23.2
Floaters/ Vitreous Opacity	16.1	3.6	1.8*	21.5
Decreased Visual Acuity/ Vision Loss	7.1	12.5	1.8	21.4
Eye Pain/ Soreness	8.9	5.4	0	14.3
Corneal Abrasion/ Epithelial Defect	1.8	8.9	0	10.7
Corneal Edema	10.7	0	0	10.7
<b>Treatment Related Serious Adverse Events (SAE, n=56)</b>				
Vision Loss (juxtafoveal tumor, n=2)			3.6	3.6

Table presents percentage of patients with AEs related to AU-011 or laser by severity and overall; patients with more than 1 AE are counted in the highest severity group SAEs are listed separately in the SAE table.

\*2 patients treated with vitrectomy – 1 with vitreous opacity and another with persistent vitreous inflammation

**Figure 16. Adverse events among all 56 patients treated with AU-011.**

The rate of treatment related AEs in the 14 patients with active tumor growth dosed with two cycles of AU-011 were similar to those reported in the overall treated population.

Small Tumor/Active Growth Patients (n=14) Key Treatment Related Adverse Events (≥10% Subjects)	Grade I (%)	Grade II (%)	Grade III (%)	Total (%)
Vitreous Inflammation	21.4	64.3*	7.1	92.8
Anterior Chamber Inflammation	35.7	35.7	7.1	78.5
Peritumoral RPE/ Pigmentary Changes	57.1	7.1	0	64.2
Increase in Intraocular Pressure	14.3	35.7	0	50.0
Decreased Visual Acuity/ Vision Loss	0	35.7	0	35.7
Corneal Abrasion/ Epithelial Defect	0	21.4	0	21.4
Floaters/ Vitreous Opacity	7.1	14.3	0	21.4
Eye Pain/ Soreness	14.3	7.1	0	21.4
Posterior Synechiae	14.3	0	0	14.3
Corneal Edema	14.3	0	0	14.3
Corneal Disorder	14.3	0	0	14.3
<b>Treatment Related Serious Adverse Events (n=14)</b>				
Vision Loss (juxtafoveal tumor, n=1)			6.7	6.7

Table presents percentage of patients with AEs related to AU-011 or laser by severity and overall; patients with more than 1 AE are counted in the highest severity group  
SAEs are listed separately in the SAE table.  
\*1 patient treated with vitrectomy due to persistent vitreous inflammation

**Figure 17. Adverse events reported among the 14 patients with active tumor growth treated with two cycles of AU-011.**

Adverse events of pigmentary changes around the tumor margin were reported in approximately 38% of patients and were the cause of the only two drug-related serious adverse events, or SAEs, of vision loss. In these two subjects the edge of the tumor was within 1.0 mm of the fovea and the pigmentary changes occurred in the fovea causing the vision loss of greater than 30 letters. Other pigmentary changes around the tumor outside of the fovea had minimal clinical impact and did not cause a loss of visual acuity, which suggests that the location of the tumor was in part responsible for the two SAEs. While the cause of these pigmentary changes is unknown, we believe that based on clinical observations they may be related to an immune response. A risk mitigation strategy that was included as a protocol amendment after the first SAE occurred was to limit the dose of laser in the fovea to only one laser activation per treatment, instead of two activations which is the dose given otherwise. Two SAEs that were not related to treatment were reported in two patients, one event each of papillary renal cell carcinoma and diverticulitis.

A high proportion of patients (43/56; 77%) in the trial were at high risk for vision loss with radiotherapy because their tumors were close to the fovea or optic disk (<3.0 mm). If these patients had been treated with radiotherapy, historical studies suggest that a large proportion would have a worse visual acuity prognosis, with many having vision of <20/200 or legal blindness within five years. Approximately 90 percent of high-risk patients with tumors near the fovea or optic nerve had a significant vision loss with plaque brachytherapy as the plaque led to irreversible damage to the fovea or optic nerve. In contrast, most of the high-risk patients in our trial were successfully treated with AU-011 without a significant impact on their visual acuity, highlighting the potential benefit relative to the current standard of care. A cross trial comparison of patients treated with AU-011 and patients treated with plaque brachytherapy highlights the stark differences in the adverse event profiles between current standard of care therapy and AU-011.

Adverse Event	Radiotherapy
Surgeries secondary to AEs	~40%
Radiation Retinopathy	~40%
Neovascular Glaucoma	10%
Dry Eye Syndrome	20%
Strabismus	2%
Retinal Detachment	1-2%
Vision Loss ( $\geq 15$ letters)	~70%

Serious Adverse Event	Radiotherapy
Scleral Necrosis	0-5%
Enucleation/Eye Loss	10-15%
Vision Loss in High-Risk Subjects ( $\geq 30$ letters)	~90%

**Figure 18. Treatment related adverse event rates with plaque brachytherapy**

Adverse Event	AU-011
Surgeries secondary to AEs	~13%
Radiation Retinopathy	0%
Neovascular Glaucoma	0%
Dry Eye Syndrome	~2%
Strabismus	0%
Retinal Detachment	~2%
Vision Loss ( $\geq 15$ letters)	~21%

Serious Adverse Event	AU-011
Scleral Necrosis	0%
Enucleation/Eye Loss	0%
Vision Loss in High-Risk Subjects ( $\geq 30$ letters)	4.6%*

\* 77% (43/56) of patients in Ph1b/2 IVT trial were at high risk for vision loss; 2/43= 4.6%

**Figure 19. Treatment related (AU-011 or laser) adverse event rates with AU-011 with IVT administration**

We believe that AU-011 has the potential to deliver meaningful clinical benefit to patients with early-stage choroidal melanoma as a first-line treatment while decreasing the likelihood of irreversible loss of visual acuity and other severe comorbidities that are often associated with radiotherapy.

*Preclinical data*

In preclinical studies, we observed that AU-011 was able to bind potently to multiple ocular melanoma human cell lines with over half of cells being bound at AU-011 concentrations below 100 pM. This binding was observed in 92.1, MP41 and MP46 cell lines, which represents a range of genetic

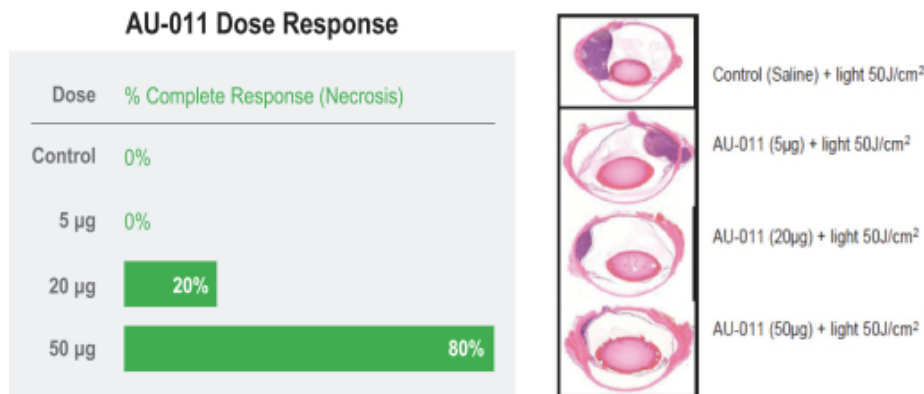
profiles. These findings are consistent with binding of AU-011 to extracellular tumor-specific HSPGs independently of the genetic alteration.

Activation of AU-011 by laser illumination resulted in potent cell killing at a picomolar level across cancer cell lines. These data support that AU-011's physical mechanism of action to cause acute cellular necrosis may be independent of the particular mutation of the melanoma. No cell killing was observed with AU-011 in the absence of laser-activation, which supports our hypothesis that AU-011 only gains cytotoxicity upon activation with near infrared light when bound to the tumor cell.



**Figure 20. AU-011 leads to laser-activation-dependent killing of multiple ocular melanoma cell lines.**

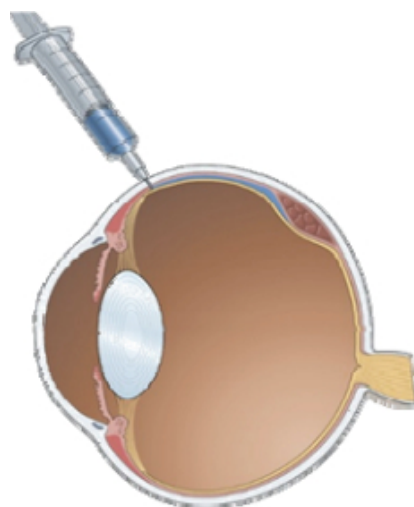
We investigated the efficacy of AU-011 in an orthotopic rabbit ocular melanoma model that closely mimics human disease and uses the 92.1 human choroidal melanoma cells. We administered AU-011 by intravitreal injection or SC administration and laser activation in the exact same manner as in clinical practice. We observed dose-dependent tumor necrosis. At a dose of 50 µg, laser-activated AU-011 given twice weekly by intravitreal administration, on day 1 and day 8, resulted in 80% (four of five) of eyes with complete tumor necrosis. Importantly, this was in large tumors with thickness up to approximately 5 mm to 10 mm, which is three to four times larger than what we are targeting in our clinical trials.



**Figure 21. AU-011 caused dose dependent response and tumor necrosis confirmed by histopathology in rabbit ocular melanoma model.**

*Suprachoroidal delivery*

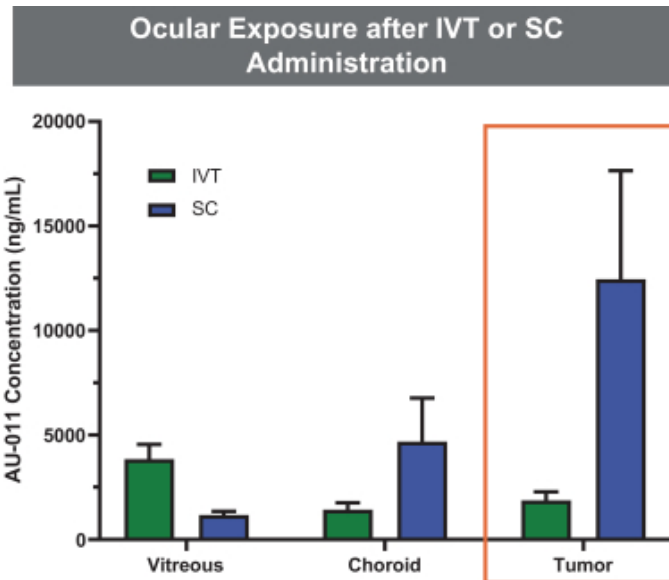
As part of our overall development strategy, we are evaluating and developing the SC route of administration to optimize the delivery of AU-011 to the choroid where the tumor is located. The suprachoroidal space, or SCS, is a potential space bound between the external surface of the choroid and the internal surface of the sclera, and encompasses the full circumference of the full posterior segment of the eye.



**Figure 22. Suprachoroidal administration with SCS Microinjector™.**

Our preclinical data supports the SCS as an attractive site for intraocular drug delivery for choroidal melanoma for multiple reasons:

- Optimization of the therapeutic index due to increased bioavailability at the tumor and lower exposure to key ocular structures as seen below in Figure 23.
  - a. In a rabbit choroidal melanoma model, we observed five times higher tumor exposure was obtained with SC versus intravitreal administration.
  - b. We also observed lower levels in the vitreous, which may translate into lower risk of intraocular inflammation and may lead to less vision loss.
- Optimization of the treatment duration in the clinic reduces the time between the injection and the laser activation due to faster distribution.
- Injection procedure which requires minimal training.
- We believe increased bioavailability may enable treatment of a broader range of patients with medium-sized choroidal tumors, including melanomas and choroidal metastases.



**Figure 23. Suprachoroidal administration in a rabbit tumor model led to increased drug concentrations in tumors and lower concentrations in vitreous than intravitreal administration.**

*Phase 2 suprachoroidal administration trial*

We are currently conducting a Phase 2 dose escalation trial of AU-011 with SC administration in 18 patients with choroidal melanoma. The primary objective of this portion of the trial is to determine the maximum tolerated dose and treatment regimen. We believe SC administration can result in a better target product profile with reduced inflammation because of significantly lower exposure of the drug to the vitreous and potentially higher clinical activity than intravitreal administration because of increased drug exposure to the tumor in the choroid.

The results from the initial patient cohorts with an average of six months follow-up demonstrated that SC administration was generally well tolerated with no serious treatment related adverse events reported. To date, drug and laser related adverse events have included three patients with mild anterior uveitis, two patients each with both punctate keratitis and eye pain, and one patient with conjunctiva hyperemia, conjunctival edema, eyelid edema, pupils unequal retinal pigment epitheliopathy, and salivary gland enlargement. One moderate adverse event of anterior scleritis related to the injection procedure was also observed. All of the events were resolved spontaneously with standard of care treatment. Of note, minimal inflammation in the vitreous has been observed in this trial through the two cycles of the highest tested dose (40 µg). Given the tolerability profile with the 40 µg dose, we increased the highest dose to 80 µg per treatment and plan to explore a new treatment regimen with three cycles of treatment. We plan to present the six to 12 month safety and efficacy data from this trial in 2022.

All Treated Subjects (n=13) Drug/Laser Related Adverse Events	Grade I	Grade II	Grade III	Total
Anterior chamber cell/ inflammation	23.1%	0	0	23.1%
Conjunctival edema	7.7%	0	0	7.7%
Conjunctival hyperemia	7.7%	0	0	7.7%
Eye pain	7.7%	7.7%	0	15.4%
Eyelid edema	7.7%	0	0	7.7%
Punctate keratitis	15.4%	0	0	15.4%
Pupils unequal	7.7%	0	0	7.7%
Retinal pigment epitheliopathy	7.7%	0	0	7.7%
Salivary gland enlargement*	0	7.7%	0	7.7%

Table presents percentage of subjects with AEs related to AU-011 or laser by severity and overall; subjects with more than 1 AE are counted in the highest severity group  
 Data cutoff Sep 15, 2021 \*Likely related to COVID vaccine per investigator

**Figure 24. Adverse events among the 13 patients enrolled in the Phase 2 suprachoroidal trial to date.**



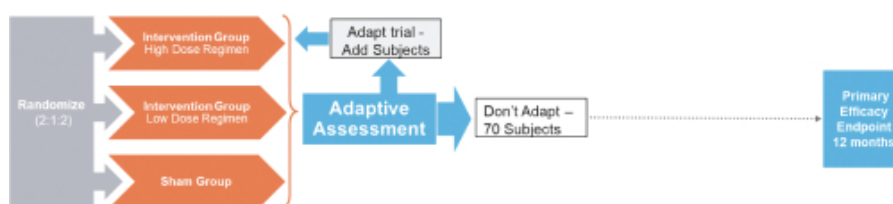
\*2 subjects were planned, third subject was enrolled due to a lower dose administered in error in 1 subject.

**Figure 25. Phase 2 clinical trial design with suprachoroidal administration. Dose escalation cohorts.**

*Pivotal trial plan in choroidal melanoma*

In alignment with the FDA and EMA, we plan on conducting two pivotal trials with AU-011. The first pivotal trial will be the Phase 2b portion of the ongoing SC administration trial. We anticipate initiating this portion in the second half of 2022 in patients with high-risk indeterminate lesions and small choroidal melanoma who have active growth prior to enrollment. We intend to randomize a minimum of 70 patients in this trial to three arms 2:1:2 to receive therapeutic regimen AU-011, low dose regimen AU-011 or a sham control. Patients will be selected based on having a small amount of active growth within two years of trial enrollment, and a tumor size of 0.5 mm to 3.0 mm in thickness and less than 10 mm in diameter.

## Pivotal Trial



**Figure 26. Preliminary design of the pivotal trial.**

The key primary endpoint agreed with the FDA is contemplated to be the tumor thickness growth rate over 12 months, comparing the growth rates between the AU-011 high dose group and the sham group. The first key secondary endpoint will be a composite time to event analysis that will evaluate the number of events of disease progression or visual acuity failure between the AU-011 high dose group and the sham group. We will also evaluate time to disease progression and change from baseline in BCVA letter score. There will be a minimum follow up for all patients of 12 months.

The trial has a power of >95% to meet the primary and the first key secondary endpoint. Since there is no drug approved for the treatment of choroidal melanoma, we have agreed with FDA that a statistically significant difference on these endpoints will provide support from a regulatory perspective to meet the requirement of clinical effectiveness.

Given that choroidal melanoma is a rare disease and, based on the limited natural history data of the growth rate of these early-stage tumors, this trial will follow an adaptive design with the ability to perform a sample size re-estimation. With this adaptive design, the sample size will be increased if either (1) the observed growth rate in the sham arm is lower than assumed or (2) the estimated treatment effect comparing the sham arm and the high dose arm is less than expected. With this strategy, we believe we will improve the probability of success of the trial.

We also plan to conduct a second pivotal trial, which will be a Phase 3 randomized trial, that will start enrolling when the first pivotal trial completes enrollment. This Phase 3 trial is planned to be an identical design to the Phase 2b pivotal trial described above with the same primary and secondary endpoints. The final sample size of this second pivotal trial will be determined by the final sample size of the Phase 2b pivotal trial.

If warranted by the data, we plan to submit the results of the Phase 2b pivotal trial to support approval of AU-011 for the treatment of primary indeterminate lesions and small choroidal melanoma. Based on the results of the Phase 2b pivotal trial, if positive, and the fact that there are no therapies approved for the treatment of this rare disease, the FDA and EMA may agree to grant approval based on the first pivotal trial with the condition that the second Phase 3 pivotal trial should be completed as a post-approval commitment. However, the FDA and/or EMA may require both trials for approval, which will be addressed subsequent to submission of the data from the first pivotal trial.

### **Registry Trial**

We have agreement with the FDA that we will monitor all patients for a total of five years after dosing to evaluate the long-term tumor response, visual acuity preservation and safety, as well as the risk of metastatic disease and mortality, which we are doing in a Phase 4 registry trial. To date, all 57 patients in the Phase 1b/2 trial with intravitreal administration have completed the Phase 1b/2 trial and 41 (72%) have entered the registry trial. The data collected with an average follow up of two or more years from initial enrollment in the Phase 1b/2 trial and follow up in the registry demonstrates durability of tumor control, visual acuity preservation and related safety profile from treatment of AU-011. All



subjects in the registry trial treated only with AU-011 had stable vision and no local progression of disease after up to two years of follow-up. For those patients who progressed in tumor size in the Phase 1b/2 trial and who received standard of care with radiotherapy, two patients lost visual acuity and one additional patient had to have their eye enucleated because of tumor recurrence after radiotherapy, reaffirming our belief that there is a high unmet medical need in this patient population.

Only one of 40 patients in the registry had onset of metastatic disease which is an encouraging result as usually the metastatic risk for small melanomas is approximately 12% up to 10 years' follow up.

#### ***Matched case control studies***

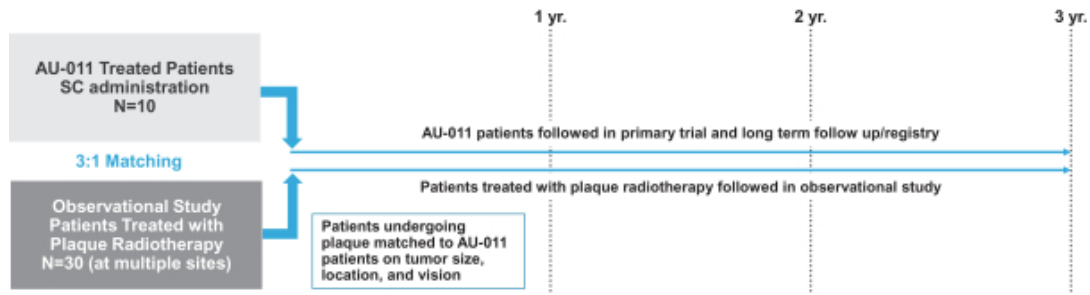
The ability to demonstrate tumor control with long term visual acuity preservation could provide a favorable benefit-risk profile of AU-011 for the first line treatment of patients with early-stage choroidal melanoma compared to an invasive radiotherapy procedure. To demonstrate the long-term value of visual acuity preservation for patients treated with AU-011, we are conducting two Matched Case Control, or MCC, studies that will provide data comparing AU-011 to radiotherapy. A retrospective MCC study has been performed to provide an estimate of the vision benefit of AU-011 versus radiotherapy and to help estimate the treatment effect and powering of the prospective MCC study that is expected to start in 2021. These studies are discussed below.

#### ***Retrospective matched case control study analysis***

To estimate the vision preservation of AU-011 compared to radiotherapy we are conducting a retrospective MCC analysis comparing the group of patients in our Phase 1b/2 trial with small tumors with active growth (n=14) to patients with tumors of similar size and location previously treated with radiotherapy at the Wills Eye Hospital Ocular Oncology Service led by Dr. Carol Shields. This analysis will match up to 5:1 patients using the key baseline characteristics that impact long term visual acuity – tumor location, tumor size and baseline visual acuity – and will compare the visual acuity after treatment with each therapy in terms of a change from baseline in vision and absolute vision at years one, two and three. Results from our Phase 1b/2 trial with intravitreal administration show visual acuity preservation in a majority of patients after two cycles of treatment with AU-011 at twelve months. In addition, data from our ongoing registry trial to date do not show a change or decline in vision for patients treated with AU-011 with long term follow up, while two patients that failed treatment with AU-011 and were treated with radiotherapy are having vision loss. We believe that the results of the retrospective study will further validate these results and strengthen our thesis that the mechanism of AU-011 enables durable preservation of visual acuity providing an important advantage to radiotherapy. The results of the retrospective study will be published with Dr. Carol Shields in the first half of 2022 and will be used to estimate the assumptions to power a prospective Matched Case Control study that we plan to start shortly thereafter.

#### ***Prospective matched case control study***

Based on the results of the retrospective MCC analysis we are initiating a prospective matched case control trial where we will compare, after one, two, and three years, the visual acuity of patients treated with AU-011 versus patients treated with radiotherapy. Like the retrospective MCC analysis, patients will be matched based on similar tumor size, location, and baseline vision at the beginning of the trial.



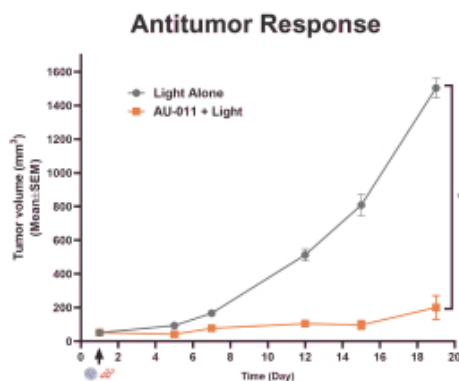
**Figure 27. Matched case control prospective trial comparing visual acuity outcomes after treatment with AU-011 or plaque radiotherapy.**

The patients are planned to be matched on average 3:1 (Radiotherapy: AU-011) to increase the power. The matching and analysis will be masked and performed independently. The objective is to show the vision benefit of AU-011 compared to radiotherapy using prospective data for both groups. Based on initial results in the retrospective MCC study, we believe these results may support the benefit/risk discussion of our regulatory submission and to serve as support for pricing and reimbursement discussions.

***Choroidal metastases from other tumors***

We can apply our mechanism of action for AU-011, which we believe has the ability to preserve key ocular structures, in multiple other ocular oncology indications. Beyond primary choroidal melanoma, we are developing AU-011 in additional ocular oncology indications, starting with choroidal metastases. Choroidal metastases are a common intraocular malignancy that are caused by multiple primary cancers in the body that metastasize to the eye due to the high blood flow and perfusion that provides an environment receptive to metastases and tumor growth. Approximately 22,000 patients have choroidal metastases globally every year, and approximately half (~47%) of the patients with choroidal metastases have primary breast tumors. Other common primary cancers include lung (approximately 21%), gastrointestinal (4%), kidney (2%), cutaneous melanoma (2%) and prostate cancer (2%), and approximately 17% of cases with an unknown primary tumor type. The majority of these malignancies are solitary small tumors in the choroid associated with subretinal fluid and, as opposed to choroidal melanoma, they can occur in and adversely affect vision in both eyes. These lesions are typically treated with radiation, which has the same comorbidities as previously described for the treatment of choroidal melanoma. Given their poor prognosis, the quality of life and, in particular, maintenance of vision, for patients with metastatic cancer is critical and as such there is a significant unmet need for an effective vision sparing ocular treatment that enables patients to avoid additional surgical interventions.

We have observed in preclinical experiments that treatment with AU-011 led to HSPG-dependent tumor cell binding and laser-activation-dependent cell killing of multiple cell lines in each of the common primary tumors listed above as well as multiple other primary solid tumors. We believe this versatility makes AU-011 a good potential treatment option for choroidal metastasis. AU-011's mechanism of action does not depend on specific mutations in the genetic profile of the tumor or on the expression of a particular type of growth factor receptor, but rather on the ubiquitously expressed tumor modified HSPGs on the cell membrane of solid tumors. For example, in a mouse EMT-6 breast cancer model, treatment with a single intravenous administration of 100 µg dose of AU-011 followed twelve hours later by laser activation led to significant reduction in tumor growth rate compared to placebo controls.



**Figure 28. Single dose of AU-011 treatment led to significant reduction in tumor growth in an EMT-6 breast cancer model.**

Based on the results we observed in our choroidal melanoma Phase 1b/2 trial and the preclinical results we have observed with AU-011 in these multiple cancers *in vitro* and *in vivo*, we believe that AU-011 has the potential to treat choroidal metastases and preserve vision.

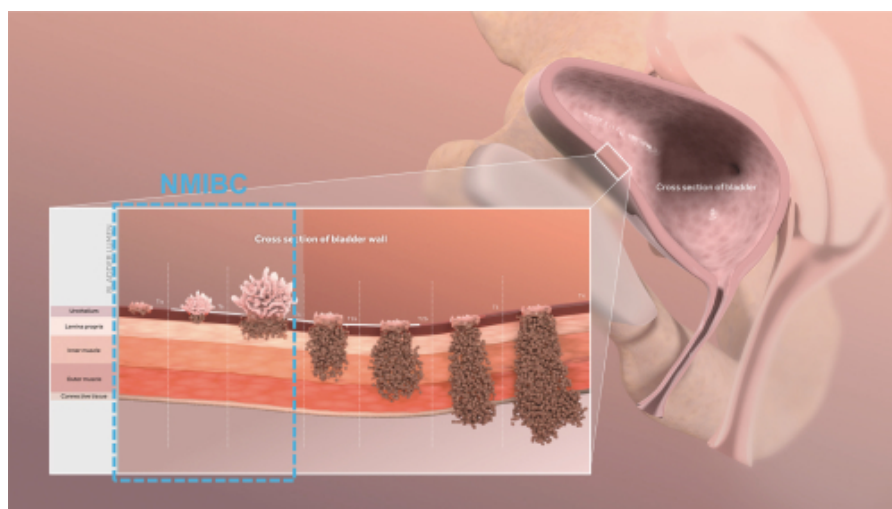
We are planning to initiate clinical development in this indication in the second half of 2022, subject to FDA acceptance of an IND.

#### **AU-011 for the treatment of non-muscle-invasive bladder cancer**

We are developing AU-011 for the treatment of NMIBC. We are planning to initiate clinical development with AU-011 with intramural administration, a novel route of administration for the treatment of patients with intermediate and high-risk bladder cancer lesions. This novel route of administration is based on the direct administration of AU-011 into the lamina propria of the bladder wall at the tumor edge. It is intended to place high levels of AU-011 at the base of the tumor where laser activation can cause localized necrosis preventing residual tumor cells from further growth and recurrence. We are conducting IND-enabling studies with AU-011 to demonstrate the feasibility of this approach and intend to begin clinical trials in the second half of 2022.

##### *Bladder cancer disease background*

Bladder cancer is the most common malignancy involving the urinary system and is the eighth most common cause of cancer death in men in the United States. Estimates are that there will be 61,300 new cases of bladder cancer and 17,000 deaths in 2021 in the United States. Globally, bladder cancer accounts for approximately 570,000 cases, with 422,000 cases comprised of NMIBC, and 165,000 deaths each year. Patients with bladder cancer classically present with painless blood in the urine, however, because this symptom is like those of benign disorders such as urinary tract infections, cystitis, prostatitis and the passage of kidney stones, the diagnosis of bladder cancer is often delayed while these other, more common, conditions are ruled out. Furthermore, symptoms are often intermittent. Delays in diagnosis can lead to a worsened prognosis due to the presence of more advanced stage disease by the time a confirmation of bladder cancer is made.



**Figure 29. Cross section of the bladder wall and staging of bladder cancer.**

Bladder cancer is classified into two broad categories: NMIBC, where the primary cancer is restricted to the urothelial layer of cells or the connective tissue under this layer in the bladder; and muscle-invasive bladder cancer, or MIBC, which is a more advanced cancer that has invaded deeper into the bladder wall and has a higher potential to metastasize. Approximately 70% of newly diagnosed cases of primary bladder cancer are NMIBC. The five-year survival for patients with early stage disease is 88%. For patients with metastatic disease or cancer that has spread to other parts of the body, however, the five-year survival drops to 15%. We believe that early treatment intervention would significantly improve the outcomes for these patients.

Early stage NMIBC is characterized by a lack of first-line treatment options. It is typically treated by surgical removal of the tumor through a procedure known as transurethral resection of bladder tumor, or TURBT, in which an endoscope is inserted through the urethra into the bladder allowing tumor removal without requiring incisions. Depending on the stage of the tumor, this is followed by local chemotherapy or Bacillus Calmette-Guerin, or BCG, that is instilled into the bladder. Despite this treatment many of these cancers recur and spread throughout the bladder.

For high risk and intermediate risk patients, the most common non-surgical therapy used today is intravesical immunotherapy with BCG, a live attenuated form of *Mycobacterium bovis* that has been used to treat bladder cancer for over forty years. While the exact mechanism of action of BCG is unknown, it is believed that infection of the bladder with BCG triggers a local immune response and the accompanying heightened activation of the immune system improves its ability to recognize and destroy cancerous cells. BCG reduces tumor recurrence and progression of disease as defined by the need for surgery or additional chemotherapy. However, 30 to 40% of patients do not respond to this therapy and are at risk of developing advanced disease. The recommended treatment for these patients is radical cystectomy, which is a surgical procedure where the entire bladder and other local structures are removed. In men, this procedure typically includes removal of the prostate and seminal vesicles. In women, radical cystectomy also involves removal of the uterus, ovaries, and part of the vagina.



**Figure 30. NMIBC is categorized and treated based on risk stratification, determined by combination of tumor grade, stage, size, recurrence history and focality.**

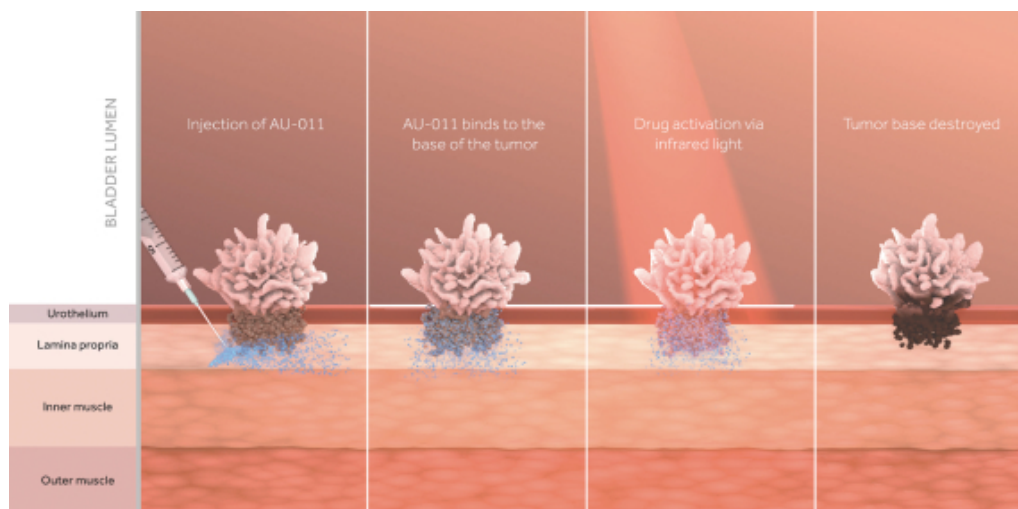
Beginning in January 2019, Merck & Co., the world’s only manufacturer of BCG, announced a global shortage of BCG for the foreseeable future due to its growing use and supply constraints. In response to this shortage, urological cancer advocacy groups advised that BCG not be used for low-risk patients. They also advised that if the standard dose is unavailable due to supply constraints, high-risk patients only receive one-half to one-third the standard dose in order to postpone surgical intervention or to slow progression of disease. These alterations in guidelines that limit available BCG for patients have resulted in suboptimal patient care. This has driven clinicians to evaluate alternative therapeutics to ensure adequate patient care which underscores the need for continued innovation in NMIBC.

The most common treatment for patients diagnosed with advanced or metastatic bladder cancer is chemotherapy with platinum-based drugs such as carboplatin or cisplatin in combination with gemcitabine. Patients with metastatic disease that progresses during or after platinum-based chemotherapy are increasingly being treated with checkpoint immunotherapy. Several agents targeting the programmed cell death-1, or PD-1, pathway have been approved by the FDA for use in refractory metastatic bladder cancer. Objective response rates for advanced metastatic bladder cancer reported in clinical trials with checkpoint inhibitors have been between 23% and 33%. The historical median overall survival of patients with advanced or metastatic bladder cancer from the start of initial therapy is 12.7 months.

We believe that a targeted therapy for the primary tumor directed specifically to bind to and kill bladder cancer cells and subsequently activate the immune system has the potential to generate long-term antitumor immunity that may prevent recurrence in patients with early-stage disease.

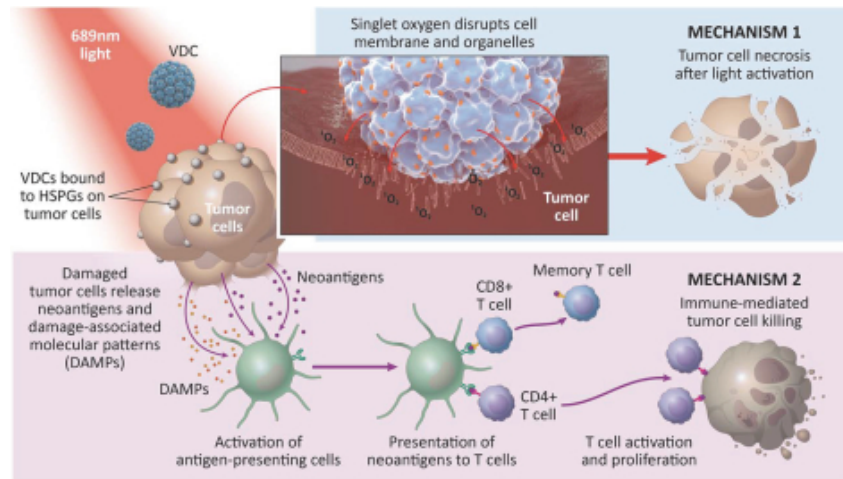
***Our solution AU-011***

We are currently developing AU-011 for the treatment of NMIBC with IND-enabling studies and plan to initiate a Phase 1a trial in the second half of 2022, subject to FDA acceptance of an IND, to evaluate the feasibility of intramural administration and to assess distribution, safety and initial proof of mechanism with evaluation of local acute cellular necrosis after laser activation. We believe AU-011 represents a potential targeted therapy that can be activated using a similar laser as that currently utilized in our choroidal melanoma program, following a well-characterized approach with commercially available devices used by urologists.



**Figure 31. AU-011 is administered in the lamina propria close to the base of the tumor where it selectively binds tumor cells. Upon laser activation, AU-011 leads to acute tumor cell necrosis and immune activation preventing tumor cells at the base of the tumor from further growth and recurrence.**

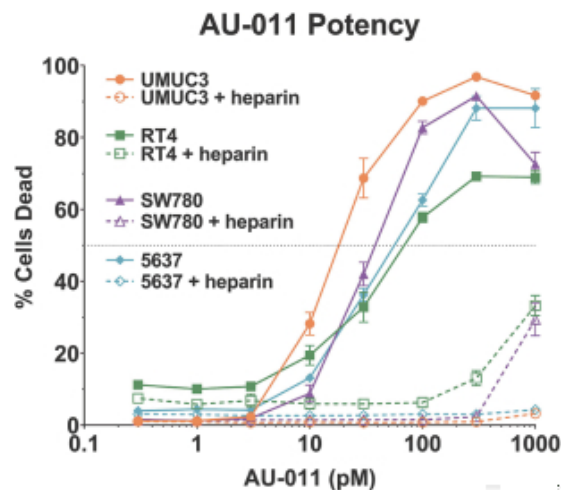
AU-011 has been observed to be highly selective, through both its specific binding to modified HSPGs on cancer cells, combined with focused laser activation leading to cytotoxicity and subsequent immune activation. We believe the immune response could play an even larger role in bladder cancer, given that bladder cancer has a well-documented response to immune activation. This immune sensitivity is substantiated by the effectiveness of immune modulatory agents like BCG. We have observed in preclinical experiments that AU-011 was able to target bladder cancer cells in both *in vitro* and *in vivo* tumor models. Laser activation of AU-011 resulted in cell killing of bladder tumor cells while sparing other normal surrounding cells as a single agent. This cell killing induced a pro-immunogenic antitumor response that resulted in complete elimination of tumors in a mouse xenograft model and durable responses as well as the prevention of tumor re-implantation. This highlights the value of AU-011 to generate antitumor immunity and prevent tumor recurrence. Based on our preclinical data, AU-011 was also observed to be highly synergistic with checkpoint inhibitors that have already been approved for the treatment of a subset of NMIBC and metastatic bladder cancer patients.



**Figure 32. Overview of AU-011's dual mechanism of action with acute tumor cell necrosis and secondary antitumor immunity.**

*Preclinical data*

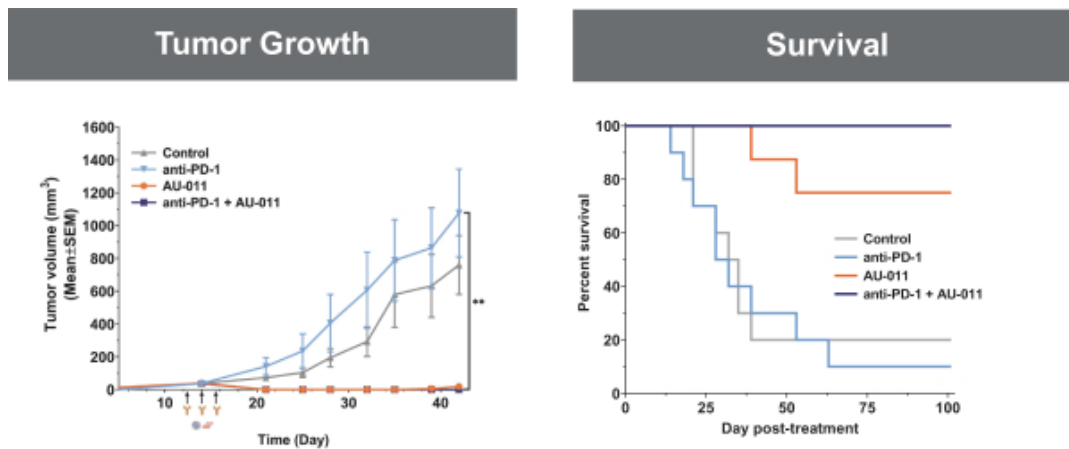
In preclinical studies AU-011 demonstrated binding with high affinity to multiple bladder cancer cell lines at very low concentrations of less than 100 pM. This robust multivalent binding was dependent on the presence of HSPGs on the cancer cell surface. To show the specificity of binding to HSPGs on tumor cells, we pre-incubated AU-011 with heparin, which blocked the heparin binding sites on AU-011 and prevented it from binding to HSPGs on the tumor cell membrane. Furthermore, no cytotoxicity was observed. In contrast, without the presence of heparin, laser activation of AU-011 led to killing of cells from all four bladder cancer cell lines tested. This highlights the requirement of HSPGs binding to tumor cells in order to initiate a potent cytotoxic effect, suggesting that not only is the cytotoxic payload inert when free, but that AU-011 is required to be bound to be effective. We believe that these attributes will help limit off-target and off-tumor toxicity, which may limit the local and systemic toxicity observed in other treatments like BCG, and ultimately may result in patients not requiring cystectomy.



**Figure 33. AU-011 is effective in killing multiple bladder cancer cell lines.**

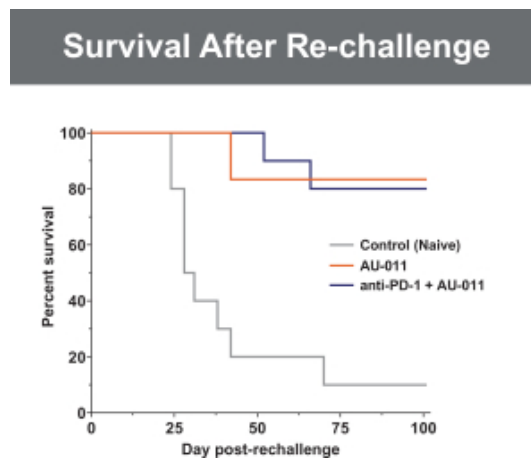
We have generated *in vivo* data in immunocompetent murine tumor models of bladder cancer that show a dose-dependent cytotoxic response of AU-011 with an upregulation of markers of immunogenic cell death, such as calreticulin and HSP70, which are DAMP molecules.

A single systemic dose administration of AU-011 in the MB49 syngeneic bladder cancer model led to cell death and elimination of the primary tumors, resulting in complete responses in 80% of animals. Combination with an anti-PD-1 immune checkpoint inhibitor antibody improved therapeutic activity resulting in a 100% complete response rate and survival that was durable at least 100 days post-treatment.



**Figure 34. AU-011 *in vivo* effect on tumor growth and survival in a bladder cancer model.**

In this model, we observed that treatment with AU-011 was able to generate a long-term immune response that further prevented the establishment of new bladder tumors on re-challenge 100 days after the single administration of AU-011. 80% of the mice treated with AU-011 as a single agent or in combination with an anti-PD1 antibody remained tumor free after 100 days, demonstrating a durable antitumor immunity, while mice that were not previously treated with AU-011 experienced tumor growth within days and poor survival after rechallenge.



**Figure 35. AU-011 induced an antitumor immune response that protected mice against tumor re-challenge at day 100 in a MB49 bladder cancer model.**

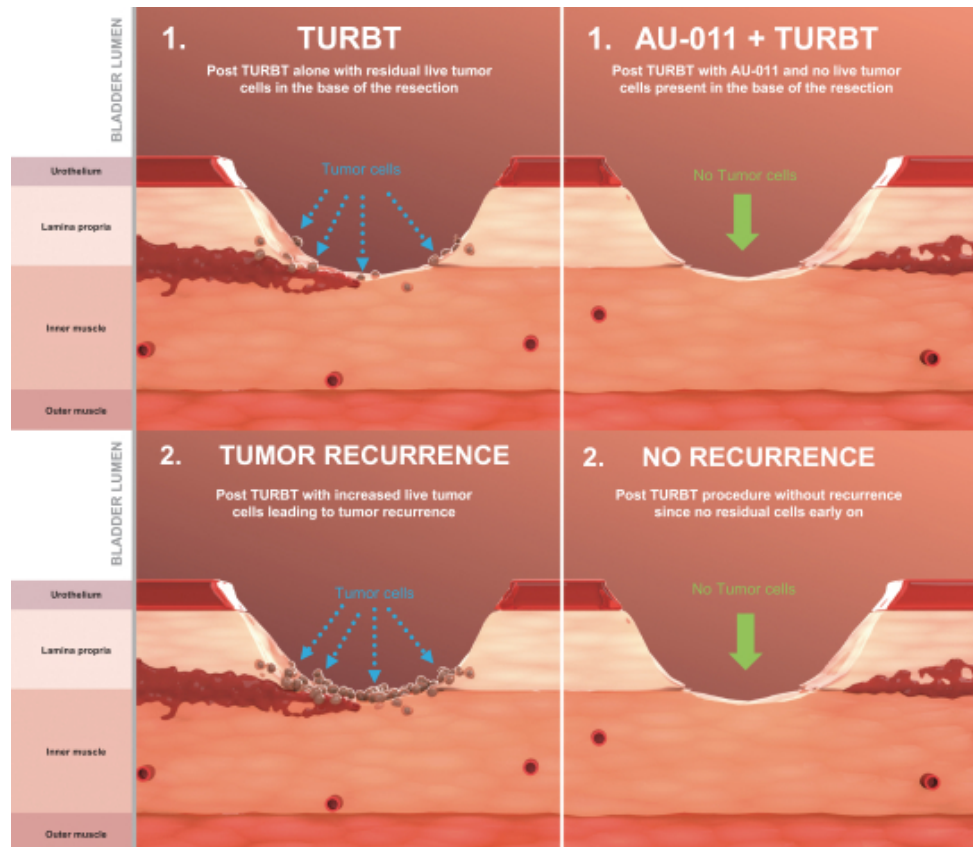


We believe that the resistance to tumor re-challenge was due to the generation of a cellular immune response following the treatment of the initial tumor 100 days earlier. Depletion of CD4+ or CD8+ T-cells at the time of AU-011 treatment or at the time of tumor re-challenge confirmed the involvement of both cell populations in the mechanism of action of AU-011 and the promotion of long-lasting antitumor immunity.

*Clinical plans in NMIBC*

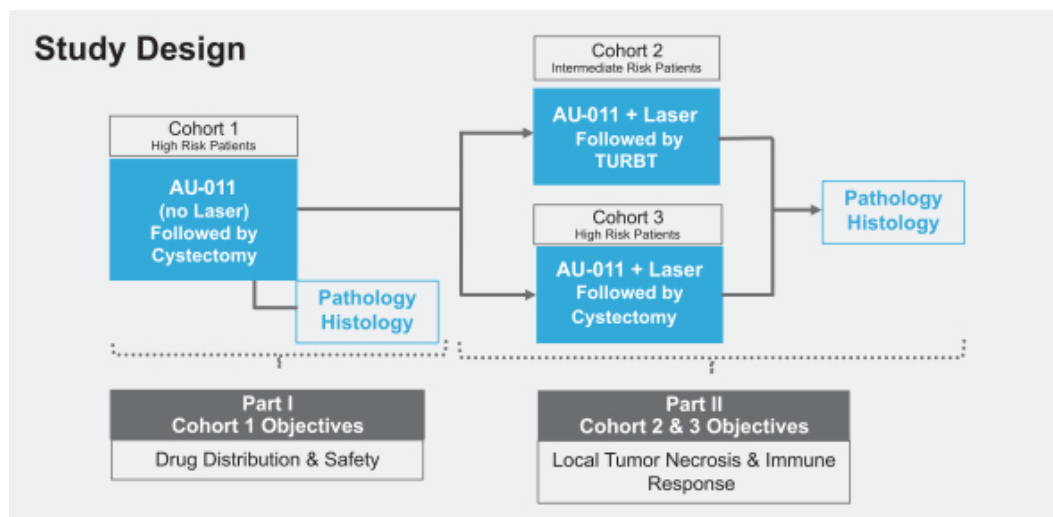
We intend to conduct a Phase 1a trial in intermediate and high risk NMIBC patients that are either candidates for TURBT or cystectomy beginning in the second half of 2022, subject to FDA acceptance of our IND. We plan to evaluate the safety, tolerability and feasibility of AU-011 using the intramural route of administration. After removal of the tumors, we plan to further assess the tumor tissue with histopathology to evaluate the presence of acute cellular necrosis as an early sign of antitumor response.

As a “window of opportunity” trial, this trial is designed to evaluate AU-011 as a treatment before planned standard of care with TURBT or cystectomy. We believe this intramural approach could be a significant benefit as the key problem leading to tumor recurrence after TURBT is that live cancerous cells may be left in the base of the resected tumor when patients undergo the surgical procedure. In fact, researchers have recently observed that circulating tumor cells can be detected in the systemic circulation after TURBT. We believe that a neoadjuvant therapy to TURBT that could kill tumor cells at the base of the lesion while generating antitumor immunity may reduce tumor recurrence, and further prevent live circulating tumor cells, which may reduce the risk of metastatic disease.



**Figure 36. Treatment with AU-011 may reduce tumor recurrence by preventing residual live tumor cells at the base of the tumor after resection with TURBT.**

We also believe that including a group of high risk, BCG unresponsive pre-cystectomy patients may enable us to evaluate AU-011's potential to confer antitumor responses in the lesions directly treated with AU-011 and in other lesions in the bladder.



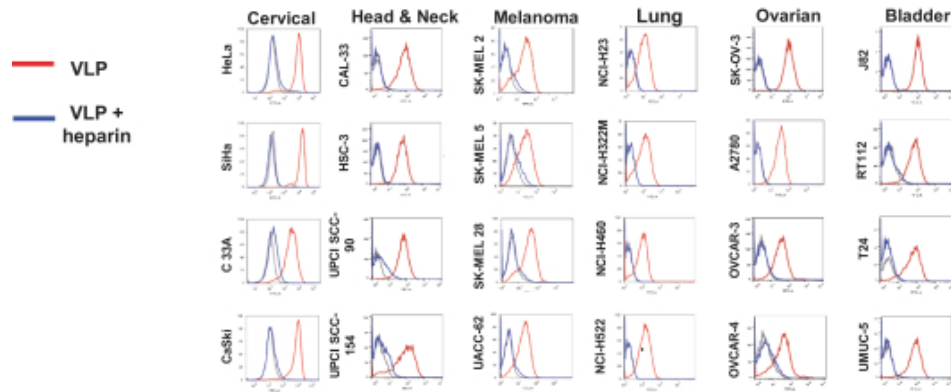
**Figure 37. Phase 1a window of opportunity trial to establish route of administration and tumor necrosis.**

In this Phase 1a trial, we intend to evaluate the tumor distribution of AU-011 after intramural administration in intermediate to high-risk subjects with NMIBC. In cohort 1, we will assess AU-011 local and systemic exposure without laser activation. In cohorts 2 and 3 we will assess AU-011 and laser activation in patients with intermediate risk that are planned to receive TURBT and high risk patients that are unresponsive to BCG and that are planned to receive cystectomy. In these cohorts, we plan to administer AU-011 followed by laser activation, and one week later the tumor will be removed by TURBT (cohort 2) or the entire bladder by cystectomy (cohort 3), and we will assess tumor response in the form of necrosis and the immune response by pathology and immunohistochemistry. This Phase 1a trial is planned to be conducted in association with the National Cancer Institute at approximately three selected private sites in the United States and is planned to be initiated in the second half of 2022.

Shortly after this initial trial, we are planning to conduct a Phase 1b/2 dose escalation and expansion trial in the treatment of NMIBC. We believe this Phase 1b/2 trial will help establish the treatment regimen and we are planning to involve multiple leading sites in the treatment of bladder cancer.

**Other HSPG-Expressing Tumors**

Our HPV-derived VLPs have a unique tropism towards cancer cells based on their multivalent binding to modified HSPGs that are specifically found in tumor cells. *In vitro*, we have observed our VLPs bind to multiple cancer cell lines. *In vivo*, we have also observed binding using our HPV-derived VLPs using xenografts of human tumor cell lines and allografts of murine tumor cell lines, like lung, ovarian, bladder, melanoma and colon. These results help to corroborate the thesis that multiple tumors appear to consistently express and specifically modify HSPGs. Accordingly, we believe we may be able to treat a broad spectrum of solid tumors. We plan to select our next solid tumor indication for clinical development with AU-011 based on its status as a tumor type with high HSPG expression, such as cutaneous melanoma and head and neck cancer.



Kines et al; International Journal of Cancer, 138:901-911, February 2016

**Figure 38. Binding of VLPs to diverse tumor types uses an HSPG-sensitive mechanism which is demonstrated by its inhibition with heparin.**

**Competition**

The biotechnology and pharmaceutical industries are characterized by rapid innovation of new technologies, fierce competition and strong defense of intellectual property. While we believe that AU-011 and our knowledge, experience and scientific resources provide us with competitive advantages, we may face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

We compete in the segments of the pharmaceutical, biotechnology, and companies focusing on developing therapies in the oncology field. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future from segments of the pharmaceutical, biotechnology and other related markets that pursue oncology therapeutics. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize AU-011 and any future product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

*Ocular oncology*

Currently we are not aware of any other company that has a drug in clinical development for the treatment of primary choroidal melanoma or for the treatment of choroidal metastases, which are our first two ocular oncology indications. The standard of care as a first line treatment for patients is plaque brachytherapy or proton beam therapy. Verteporfin (Visudyne) is currently used off label in some cases of early stage disease alone or in combination with transpupillary thermotherapy. It is possible that there may be other companies with compounds in pre-clinical development but we are not aware of any data that has been published or presented at any conference. Given our stage of development, we believe we are the furthest along in development. Our focus in ocular oncology is the treatment of the primary

cancer in the eye before it metastasizes. We are aware of other companies like Immunocore Holdings PLC, or Immunocore, that has a drug in development for metastatic uveal melanoma. Immunocore's drug is solely developed to treat metastatic disease and has not been developed to treat the early stage disease in the eye.

#### *Urologic oncology*

Currently, we are not aware of any other company that has a drug in clinical development as a neoadjuvant therapy to TURBT. Currently patients receive systemic chemotherapy after TURBT with a platinum based drug +/- Gemcitabine. There are multiple companies that have drugs in clinical development for the treatment of NMIBC patients that are unresponsive to BCG. ImmunityBio, Inc. has presented Phase 2/3 data for their drug Anktiva in combination with BCG in patients with BCG unresponsive high grade NMIBC and they plan to submit a BLA in 2021. Sesen Bio, Inc. presented Phase 3 data for their lead candidate, Vicenium, as a treatment for BCG-unresponsive NMIBC, but in August 2021 the FDA rejected its application and sent Sesen Bio, Inc. a complete Response Letter. FerGene, Inc. announced positive data of their pivotal Phase 3 clinical trial evaluating nadofaragene firadenovec (rAd-IFN/Syn3), an investigational gene therapy, for the treatment of high-grade, BCG-unresponsive NMIBC, however, they have announced delays due to chemistry, manufacturing and controls problems, so it is uncertain when they marketing application will be submitted. UroGen Pharma Ltd. has a drug Jelmyto, a gel reformulation of mytomicin that is currently approved to treat low grade upper tract urothelial cancer, which is currently in Phase 3 development for the treatment of NMIBC. CG Oncology, Inc. has a drug (CG0070) that is being investigated in a global Phase 3 clinical trial as a monotherapy for the treatment of BCG-unresponsive NMIBC.

### **Our License Agreements**

#### *NIH Patent License Agreement*

In September 2013, we entered into an exclusive patent license agreement, or the NIH License Agreement, with the NIH for certain intellectual property rights, as amended in September 2015, August 2018 and April 2019. Under the NIH License Agreement, NIH granted us a worldwide, exclusive, sublicensable license to certain patent rights related to VLPs and papilloma pseudovirus for our development and use in combination with our proprietary nanoparticle encapsulation technology both (1) for the treatment, diagnosis and imaging of cancer tumors and metastases as well as their respective pre-cursor dysplasia states and (2) conjugated with light activated drugs for the diagnosis and treatment of cancer tumors and metastases as well as their respective pre-cursor dysplasia states.

Pursuant to the NIH License Agreement, we are required to use commercially reasonable efforts to develop the licensed products using the licensed processes to make the licensed products available to the United States public on reasonable terms, including by adhering to a commercial development plan and meeting specified benchmarks with regards to specified deadlines for regulatory filings, initiation of clinical trials, and gaining regulatory approval for the licensed products.

In consideration of the rights granted under the NIH License Agreement, we paid NIH a one-time upfront payment of \$0.1 million. We are required to make low single-digit percentage royalty payments based on specified levels of annual net sales of licensed products subject to certain specified reductions. We are required to make development and regulatory milestone payments up to \$0.7 million in the aggregate and sales milestone payments up to \$0.6 million in the aggregate. We are also required to pay NIH a mid-single to low teen-digit percentage of any sublicensing revenue we receive. Additionally, our payment obligations to NIH are subject to an annual minimum royalty payment of low five figures. As of June 30, 2021, we have paid NIH approximately \$0.4 million in aggregate milestones under the NIH License Agreement. In addition to milestones under the agreement, we reimburse the NIH for any patent prosecution costs incurred. As of June 30, 2021, we have reimbursed the NIH approximately \$0.3 million in aggregate.

The NIH License Agreement will terminate upon the last expiration of the patent rights or we may terminate the entirety of the agreement upon written notice thereof to NIH. The expiry of the last to expire patent licensed under the agreement is September 2034.

During the years ended December 31, 2020 and 2019, we paid \$0.02 million and \$0.2 million, respectively, in fees associated with the NIH License Agreement. During the six months ended June 30, 2021 and 2020, we didn't pay any fees associated with the license.

#### ***LI-COR Exclusive License and Supply Agreement***

In January 2014, we entered into an Exclusive License and Supply Agreement, or the LI-COR Exclusive License Agreement, with LI-COR, Inc., or LI-COR, for the license of IRDye 700DX and related licensed patents for the treatment and diagnosis of ocular cancers, ocular pre-cancer and indeterminate lesions in humans, and as amended in January 2016, July 2017, April 2018 and April 2019. The LI-COR Exclusive License Agreement required a one-time upfront license issue fee of \$0.1 million and requires aggregate milestone payments of up to \$0.2 million upon certain regulatory and development milestones. We are also required to pay LI-COR low-single digit royalties on net sales.

The term of the LI-COR Exclusive Agreement expires on a country-by-country basis, until the longer of (i) ten years from the first commercial sale of a licensed product in such country and (ii) the last to expire valid claim in such country. The expiry of the last to expire patent licensed under the agreement is December 2023.

#### ***Clearside License Agreement***

In July 2019, we entered into a license agreement, or the Clearside License Agreement, with Clearside Biomedical, Inc., or Clearside, for the license of Clearside's suprachoroidal microinjector technology. Upon execution of the Clearside License Agreement, we paid Clearside a one-time upfront payment of \$0.1 million. Under the Clearside License Agreement, we are required to pay milestones up to \$21.0 million in the aggregate to Clearside upon the achievement of specified regulatory and development milestones, and upon the achievement of certain commercial sales milestones. We are also required to pay low to mid-single digit royalties on net sales. If we sublicense a product for which royalties are payable, then we are required to pay the greater of 20% received or low single digit royalties on net sales.

The Clearside License Agreement expires on a country-by-country basis upon the later of the last to expire patent or ten years from the date of the first commercial sale of a product. The expiry of the last to expire patent licensed under the agreement is August 2034.

#### **Intellectual property**

Our success depends in part on our abilities to (1) obtain and maintain proprietary protection for our lead virus-like drug conjugate product candidate belzupacap sarotalacan (AU-011), (2) defend and enforce our intellectual property rights, in particular, our patent rights, (3) preserve the confidentiality of our know-how relating to, for example, certain manufacturing steps, material components and characteristics of our formulations, and (4) operate without infringing valid and enforceable intellectual property rights of others. We seek to protect our proprietary position by, among other things, exclusively licensing United States and certain foreign patents and patent applications and filing United States and certain foreign patent applications related to AU-011, where patent protection is available. We also rely on know-how, continuing technological innovation and confidential information as well as pursue licensing opportunities to develop and maintain our proprietary position and protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We seek to protect our proprietary technology, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and others who may have access to proprietary information, under which they are bound to assign to us

inventions made during the term of their employment or term of service. We also seek to preserve the integrity and confidentiality of our data by maintaining physical security of our premises and physical and electronic security of our information technology systems.

We cannot be sure that patents will be granted with respect to any patent applications we have licensed or filed or may license or file in the future, and we cannot be sure that any patents we have licensed or which have been granted to us, or patents that may be licensed or granted to us in the future, will not be challenged, invalidated or circumvented or that such patents will be commercially useful in protecting our technology. For more information regarding the risks related to our intellectual property, see “Risk factors—Risks related to our intellectual property.”

Our patent portfolio includes a combination of issued patents and pending patent applications that are owned by us, co-owned by us or licensed by us from third parties. As of September 16, 2021, we have an exclusive license (with regard to ocular cancers) and a non-exclusive license (with regard to solid tumors in humans for a specific indication) from LI-COR under one issued United States patent; an exclusive license from NIH under four issued United States patents and three issued foreign patents; an exclusive license from INSERM-TRANSFERT (Inserm) under three issued United States patents, and six granted foreign patents; and exclusive rights under a Cooperative Research and Development Agreement (CRADA) with the United States Department of Health and Human Services (DHHS), as represented by the National Cancer Institute, and Institute, Center, or Division of the NIH, under three issued United States patents, two pending non-provisional United States patent applications, eight foreign patents, and eleven pending foreign patent applications.

In addition, as of September 16, 2021, we solely own four issued United States patents, one pending United States provisional application, and one pending international Patent Cooperation Treaty patent application. We intend to pursue, when possible, additional patent protection, including composition of matter, method of use and process claims related to AU-011.

**Patent families**

We license one patent family from LI-COR and one patent family from the NIH, co-own and license one patent family from Inserm, co-own two patent families with DHHS/NIH and have exclusive rights under a CRADA, and solely own two patent families, all of which are generally directed to the AU-011 product and related methods of use and production.

The first family, licensed from LI-COR, includes one issued United States patent. This patent includes claims directed to (1) fluorescent phthalocyanine dyes and (2) processes for making the dyes (e.g., the IRDye 700DX<sup>®</sup> dye molecules used in AU-011). This patent has a standard expiration date of October 23, 2023, subject to potential extensions.

The second family, licensed from NIH, includes four issued United States patents, one issued European patent, and one issued patent in each of Australia and Canada. Patents in this family include claims directed to (1) methods for inhibiting the proliferation of and/or killing cancer cells using a therapeutic agent formulated with a papilloma virus-like particle, (2) methods that include administering to a subject (e.g., a subject having a melanoma) a papilloma virus-like particle having a fluorescent dye and exposing the dye to an excitation wavelength of light, and (3) methods for detecting cancer cells using a papilloma virus-like particle having a detectable label. This patent has a standard expiration date of May 1, 2028, subject to potential extensions.

The third family, which we co-own with and license from Inserm, includes three issued United States patents, two issued European patents, an issued patent in each of Canada, Hong Kong, India and Japan. Patents in this family include claims directed to (1) a modified papillomavirus (HPV16) L1 protein having reduced immunogenicity relative to wild-type HPV16 L1 protein and an FG loop having

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the specific amino acid sequence that is present in AU-011, (2) nanoparticles comprising the modified L1 protein, (3) methods of using the modified L1 protein to deliver therapeutic agents, and/or (4) methods of producing nanoparticles comprising the modified L1 protein. This patent has a standard expiration date of July 24, 2029, subject to potential extensions.

The fourth patent family, which we own, includes four issued United States patents. Patents in this family include claims directed to (1) codon-optimized nucleic acids having the particular nucleotide sequence that encodes the modified papillomavirus (HPV16) L1 protein present in AU-011, (2) methods of producing nanoparticles that include the modified HPV16 L1 protein encoded by the codon-optimized nucleic acids, and (3) methods of using the nanoparticles that include the modified HPV16 L1 protein encoded by the codon-optimized nucleic acids to deliver a therapeutic agent to a subject having cancer. This patent has a standard expiration date of February 7, 2033, subject to potential extensions.

The fifth patent family, which we co-own with DHHS/NIH and have exclusive rights under a CRADA, includes three issued United States patents, one issued European patent, an issued patent in each of Australia, Canada, Hong Kong, Republic of Korea and Mexico, two issued patents in Japan, and one pending patent application in each of the United States, Australia, Brazil, China and Europe. Patents in this family include claims directed to (1) tumor-targeting papilloma virus-like particles containing near infrared phthalocyanine dye molecules that become toxic or produce a toxic molecule upon light activation, (2) methods that include delivering the papilloma virus-like particles to an ocular tumor, and/or (3) methods of producing tumor-targeting bioconjugates that include the papilloma virus-like particles and near infrared phthalocyanine dye molecules. This patent has a standard expiration date of September 18, 2034, subject to potential extensions.

The sixth patent family, which we own, includes a pending international Patent Cooperation Treaty application with claims directed to an ophthalmic composition that includes a near-isotonic solution of virus-like particle drug conjugates in suspension. Patents issuing from national stage applications based on this international application would have a standard expiration date of March 25, 2040, subject to potential extensions.

The seventh patent family, which we co-own with DHHS/NIH and have exclusive rights under a CRADA, includes a pending patent application in each of the United States, Australia, Brazil, Canada, China, Europe, Israel and Japan. Patent applications in this family include claims to a combination therapy that uses (1) tumor-targeting papillomavirus nanoparticles containing photosensitive molecules and (2) a checkpoint inhibitor. Patents issuing from this family would have a standard expiration date of April 11, 2038, subject to potential extensions.

The eighth patent family, which we own, includes a pending United States provisional application with claims directed to a method for treating a bladder tumor by administering a therapeutic agent to a region of the lamina propria of the bladder wall that is proximate to the bladder tumor. Patents issuing from applications claiming priority to this provisional application would have a standard expiration date of September 2042 (assuming an international PCT application claiming priority to this U.S. provisional application is filed in September 2022).

### **Government Regulation**

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with our vendors, collaboration partners, contract research organizations, or CROs, and contract manufacturers, will be required to

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navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidate. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, where we initially focused our product development, the FDA regulates biologics under the FDCA and the Public Health Service Act, or PHSA, and their implementing regulations. Biologics are also subject to other federal, state and local statutes and regulations. Our product candidate, AU-011, has not been approved by the FDA for marketing in the United States.

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

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with Good Laboratory Practice, or GLP, requirements;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an Institutional Review Board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with Good Clinical Practice, or GCP, requirements and other clinical trial-related regulations to establish the safety, purity and potency of the proposed biological product candidate for its intended purpose;
- preparation and submission to the FDA of a BLA after completion of all pivotal trials, accompanied by payment of FDA user fees;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the product will be produced to assess compliance with current Good Manufacturing Practice requirements, or cGMPs, to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency;
- potential FDA audit of the clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the biologic in the United States.

### ***Preclinical and clinical trials for biologics***

Before testing any drug or biologic in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety and toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data must be submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and it must become effective before clinical trials may begin. The central focus of an IND submission is on the protocol(s) for the initial clinical study and the general investigational plan. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational product. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about



the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Some long-term preclinical testing may continue after the IND is submitted. Accordingly, submission of an IND may or may not result in FDA authorization to begin a trial. A separate protocol submission to an existing IND must also be made for each successive clinical trial conducted in the United States, each of which may begin following a 30 day period unless the FDA issues a clinical hold on the clinical trial.

The clinical stage of development involves the administration of the product 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 GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol to be conducted in the United States, and any subsequent amendments to the protocol, must be submitted to the FDA as an amendment to the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted, or by a central IRB, to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable related to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about applicable clinical trials, including clinical trials results, must be submitted within specific timeframes for publication on the [www.clinicaltrials.gov](http://www.clinicaltrials.gov) website.

While we plan to conduct any international clinical trials under our INDs, a sponsor who wishes to conduct a clinical trial outside of the United States under its IND may need to obtain waivers for certain regulatory compliance requirements such as those requiring IRB review and approval. However, the FDA does not require that all foreign clinical trials be conducted under United States INDs. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

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

- *Phase 1*—Phase 1 clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, evaluate the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- *Phase 2*—Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

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

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

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

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

#### **Expanded Access**

Expanded access, sometimes called "compassionate use," is the use of investigational products outside of intended clinical development to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. FDA regulations allow access to investigational products under an IND by the company or the treating physician for treatment purposes for the following expanded access requests: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the investigational product under a treatment protocol or treatment IND application. There is no requirement for a company to provide expanded access to its investigational product.

#### **BLA Submission and Review by the FDA**

We intend to seek data exclusivity or market exclusivity for our product candidates. Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of a biologics license application, or BLA. A BLA is a request for approval to market a new biologic for one or more specified indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed

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information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity and potency of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. A sponsor who is planning to submit a marketing application for a biological product that includes a new clinically active component, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (PSP) within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

The FDA reviews all submitted BLAs before it accepts them for filing, and may request additional information rather than accepting the BLA for filing. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets ten months from the filing date in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA filed for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each BLA must be accompanied by a user fee, and the sponsor of an approved BLA is also subject to an annual program fee. FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions may be available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA may refer an application for a biologic to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation, for example, as to whether the biologic is sufficiently safe and efficacious in a given indication for a given population and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making marketing approval decisions.

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

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition for approving the BLA to ensure that the benefits of the product outweigh its risks. The REMS could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk-minimization tools.

After evaluating the BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter will usually describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

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

#### ***Expedited development and review programs for biologics***

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs and biologics to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, priority review and Accelerated Approval.

A new biologic is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

In addition, a new drug or biological product may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical

evidence indicates that the biologic, alone or in combination with or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including priority review and Accelerated Approval. A product is eligible for priority review if it is intended to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

A product intended to treat serious or life-threatening diseases or conditions may receive Accelerated Approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than on irreversible morbidity or mortality which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

Accelerated Approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. The FDA may withdraw approval of a drug or biologic approved under Accelerated Approval if, for example, the sponsor fails to conduct the confirmatory trials in a timely manner or the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, unless otherwise informed by the FDA, the FDA currently requires, as a condition for Accelerated Approval, that all advertising and promotional materials that are intended for dissemination or publication within 120 days following marketing approval be submitted to the agency for review during the pre-approval review period, and that after 120 days following marketing approval, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Fast Track designation, Breakthrough Therapy designation, priority review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval but may expedite the development or review process.

#### ***Post-approval requirements for biologics***

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe approved products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, including not only by company employees but also by agents of the company or those speaking on the company's behalf, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties, including liabilities under the False Claims Act where products carry reimbursement under federal health care

programs. Promotional materials for approved biologics must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may impose a number of post-approval requirements as a condition of approval of a BLA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug and biologics manufacturers and their subcontractors involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our contract manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual program fee for any marketed product. The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

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

### ***Orphan Designation and Exclusivity***

Under the Orphan Drug Act, the FDA may grant orphan drug designation, or ODD, to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with either a

patient population of fewer than 200,000 individuals in the United States, or a patient population greater of than 200,000 individuals in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States of that drug or biologic. ODD must be requested before submitting a BLA. After the FDA grants ODD, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has received ODD and subsequently receives the first FDA approval for a particular clinically active component for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years from the approval of the BLA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of ODD are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received ODD. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

### ***Biosimilars and Exclusivity***

The Patent Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

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

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and regulatory interpretation of the BPCIA remain subject to significant uncertainty.

#### ***Regulation of Combination Products in the United States***

Certain products may be comprised of components, such as biologic components and device components, that would normally be regulated under different types of regulatory authorities, and by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration or significant change in dose; or
- any investigational drug, device or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device or biological product where both are required to achieve the intended use, indication or effect.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA component for combination products, although it does not preclude consultations by the lead center with other components of FDA. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a biologic-device combination product is attributable to the biologic product, the FDA center responsible for premarket review of the biologic product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office is responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

A combination product with a biologic primary mode of action generally would be reviewed and approved pursuant to FDA's biologic approval processes. In reviewing the BLA application for such a product, however, FDA reviewers in the biologics center could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA's



regulations, combination products are subject to applicable current GMP requirements for drugs, biologics and devices, including the Quality System regulations applicable to medical devices.

#### **Other Regulatory Matters**

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

#### **Coverage and Reimbursement**

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

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

Further, due to the COVID-19 pandemic, millions of individuals have lost/will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products. It is unclear what effect, if any, the American Rescue Plan will have on the number of covered individuals.

Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

### **Health Care Laws and Regulations**

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Such laws include, without limitation:

- 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 either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal false claims and civil monetary penalties laws, including the False Claims Act and Civil Monetary Penalties Law, prohibit individuals or entities from 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. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the ACA require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report to HHS information related to physician (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) payments and other transfers of value and the ownership and investment interests of such physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include payments and other transfers of value made in the previous year to certain nonphysician providers, including physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or

services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures; and

- state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts, and analogous foreign laws and regulations.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations and exclusion from participation in federal and state healthcare programs, and responsible individuals may be subject to imprisonment.

#### ***Health Care Legislative Updates***

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs, and those methods are not always specifically adapted for new technologies such as gene therapy and therapies addressing rare diseases such as those we are developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the ACA was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Prior to the Supreme Court's decision, President Biden issued an Executive Order that initiated a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures

for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic.

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

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, at the federal level, in a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

## **Regulation in the European Union**

### ***Drug Development***

In the European Union, our product candidates may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC, or the Directive, has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the Member State regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the national competent authority, or CA, and one or more independent ethics committees, or ECs. Under the current regime, all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the CA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical trial authorization, simplifying adverse-event reporting

procedures, improving the supervision of clinical trials and increasing their transparency. In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014, or the Regulation, which is set to replace the current Clinical Trials Directive 2001/20/EC. It is expected that the new Regulation will become fully applicable at the end of January 2022. The new Regulation will be directly applicable in all Member States (and so does not require national implementing legislation in each Member State), and aims at simplifying and streamlining the approval of clinical studies in the EU, for instance by providing for a streamlined application procedure via a single point and strictly defined deadlines for the assessment of clinical study applications.

We are in the process of applying to renew our status with EMA as a small and medium-sized enterprise, or SME. If we obtain SME status with EMA, it will provide access to administrative, regulatory and financial support, including fee reductions for scientific advice and regulatory procedures.

Much like the Anti-Kickback Statue 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 induce or reward improper performance generally is usually governed by the national anti-bribery laws of European Union Member States, and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

Payments made to physicians in certain European Union 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.

#### ***Drug Review and Approval***

In the European Economic Area, or EEA, which is comprised of the Member States of the European Union together with Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a marketing authorization, or MA. There are two types of marketing authorizations.

- The centralized MA is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA, and is valid throughout the entire territory of the EEA. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases, and we therefore consider our product candidates would fall within the mandatory scope of the centralized procedure. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union. Under

the centralized procedure the maximum timeframe for the evaluation of a MA application by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of a MA application considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of a MA application under the accelerated assessment procedure is of 150 days, excluding stop-clocks, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this national MA can be recognized in other Member States through the mutual recognition procedure. If the product has not received a national MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

As part of its marketing authorization process, the EMA may grant MAs for certain categories of medicinal products on the basis of less complete data than is normally required, where the benefit of immediate availability of the medicine outweighs the risk inherent in the fact that additional data are still required or in the interests of public health. In such cases, it is possible for the CHMP to recommend the granting of an MA, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional marketing authorization. This may apply to medicinal products for human use that fall under the jurisdiction of the EMA, including those that aim at the treatment, the prevention, or the medical diagnosis of seriously debilitating or life-threatening diseases.

A conditional marketing authorization may be granted when the CHMP finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, all the following requirements are met:

- the risk-benefit balance of the medicinal product is positive;
- it is likely that the applicant will be in a position to provide the comprehensive clinical data post-authorization;
- unmet medical needs will be fulfilled; and
- the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data is still required.

The granting of a conditional marketing authorization is restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete preclinical or quality data may only be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public health threats. Conditional marketing authorizations are valid for one year, on a renewable basis. The MA holder will be required to complete ongoing trials or to conduct

new trials with a view to confirming that the benefit-risk balance is positive. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data.

#### ***Compassionate Use***

Compassionate use program allow for the use of unauthorized medicines for a specific group of patients under strict conditions. The EMA provides recommendations on how a medicine should be used in a compassionate use program and the type of patient who may benefit from treatment, however the individual Member States implement their own rules in respect of the administration of such programs. Competent authorities of the Member States can also ask the EMA for an opinion on how to administer, distribute and use certain medicines for compassionate use.

Compassionate use programs are only available for a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by an authorized medicinal product. The medicinal product provided through a compassionate use program must either be the subject of an MA application or must be undergoing clinical trials.

#### ***New Chemical Entity Exclusivity***

In the EEA, new chemical entities (including both small molecules and biological medicinal products), sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization, for a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, no generic or biosimilar product can be marketed until the expiration of the market exclusivity period. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. Even if an innovative medicinal product gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained a marketing authorization based on an application with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

#### ***Orphan Designation and Exclusivity***

In the EEA, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions with either (i) affect not more than 5 in 10,000 persons in the European Union, or (ii) where it is unlikely that the marketing of the medicine would generate sufficient return in the EU to justify the necessary investment in its development. In each case, no satisfactory method of diagnosis, prevention or treatment of the condition must have been authorized (or, if such a method exists, the product in question would be of significant benefit to those affected by the condition).

In the EEA, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following marketing approval for the orphan product. This period may be reduced to six years if, at the end of the fifth year, it is established that the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. During the period of market exclusivity, marketing authorization may only be granted to a "similar medicinal product" for the same therapeutic indication if: (i) a second applicant can establish that its product, although similar to the

authorized product, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the authorized product consents to a second orphan medicinal product application; or (iii) the marketing authorization holder for the authorized product cannot supply enough orphan medicinal product. A “similar medicinal product” is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

#### ***Pediatric Investigation Plan***

In the EEA, companies developing a new medicinal product must agree upon a pediatric investigation plan, or PIP, with the EMA's Pediatric Committee, or PDCO, and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when this data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP (even where such results are negative) are eligible for six months' supplementary protection certificate, or SPC, extension, provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to two years before the SPC expires. In the case of orphan medicinal products, a two year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

#### ***PRIME Designation***

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRiority MEdicines, or PRIME, scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation, where the marketing authorization application will be made through the centralized procedure. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the European Union or, if there is, the new medicine will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the EMA's CHMP or Committee for Advanced Therapies are appointed early in PRIME scheme facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

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

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent



regulatory authorities of the Member States. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

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

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under European Union directives, the details are governed by regulations in each Member State and can differ from one country to another.

#### ***Pricing and Reimbursement***

In the European Union, pricing and reimbursement schemes vary widely from country to country. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so-called health technology assessments) in order to obtain reimbursement or pricing approval.

The European Union provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union Member States may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union Member States and parallel trade (arbitrage between low-priced and high-priced Member States) can further reduce prices. Special pricing and reimbursement rules may apply to orphan drugs. Inclusion of orphan drugs in reimbursement systems tend to focus on the medical usefulness, need, quality and economic benefits to patients and the healthcare system as for any drug. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results-based rules of reimbursement may apply.

### ***European Union Data Collection***

The collection and use of personal data, including clinical trial data, in the European Economic Area, or the EEA, governed by the GDPR, which became effective May 25, 2018. The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EU or the monitoring of the behavior of data subjects in the European Union. The GDPR enhances data protection obligations for data controllers of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for “high risk” processing, limitations on retention of personal data, special provisions for “sensitive information” including health and genetic information of data subjects, mandatory data breach notification and “privacy by design” requirements and direct obligations on service providers acting as data processors. The GDPR also imposes strict rules and restrictions on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the United States. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States may result in fines up to 20 million euros or 4% of a company’s global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to request deletion of personal information in certain circumstances, and claim material and non-material damages resulting from infringement of the GDPR.

### **Regulation in the United Kingdom**

#### ***Brexit and the Regulatory Framework in the United Kingdom***

The UK’s withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty concerning the future relationship between the UK and the EU. The impact of Brexit on the ongoing validity in the UK of current EU authorizations for medicinal products, whether granted through the centralized procedure, decentralized procedure or mutual recognition, and on the future process for obtaining marketing authorization for pharmaceutical products manufactured or sold in the UK remains uncertain. On December 24, 2020, the EU and UK reached an agreement in principle on the framework for their future relationship, the EU-UK Trade and Cooperation Agreement, or the Agreement. The Agreement primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Although the body of the Agreement includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the Agreement. The Annex provides a framework for the recognition of GMP inspections and for the exchange and acceptance of official GMP documents. The regime does not, however, extended to procedures such as batch release certification. Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a third country. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules. As part of the Agreement, the EU and the UK will recognize Good Manufacturing Practice (GMP) inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The Agreement also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release for a period of at least two years until January 1, 2023. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use. As regards marketing authorizations, Great Britain will have a separate regulatory submission process, approval process and a separate national MA. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission.

### ***Clinical Trials***

The UK has implemented Directive 2001/20/EC into national law through the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended), and therefore UK legislation currently is broadly aligned with the position in the European Union, where Member State regimes are derived from Directive 2001/20/EC. The extent to which the regulation of clinical trials in the UK will mirror the new European Union Regulation once that comes into effect is unknown at present.

### ***Great Britain Marketing Authorizations***

As a result of the Northern Irish Protocol, centralized European Union MAs will continue to be recognized in Northern Ireland. A separate MA is, however, required in order to place medicinal products on the market in Great Britain.

On January 1, 2021, all medicinal products with a current centralized MA were automatically converted to Great Britain MAs. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, the UK medicines regulator, may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain MA. This is known as the EC Decision Reliance Procedure, or ECDRP. Under the ECDRP, submission of an MA application can be submitted to the MHRA at any time after the approval of a European Union MA; however, a delay in submission may affect the delivery of a decision within the specified timelines. Where a submission is made within five days of a positive opinion issued by the CHMP, the MHRA will aim to determine the Great Britain MA as soon as possible after European Commission approval, and by day 67 at the latest provided that the European Commission decision has been received.

The MHRA also offers a 150-day assessment timeline for all high quality applications for a UK, Great Britain or Northern Ireland MA. The 150-day timeline does not include a "clock-off" period which may occur if issues arise or points require clarification following an initial assessment of the application. Such issues should be addressed within a 60-day period, although extensions may be granted in exceptional cases.

### ***Early Access to Medicines Scheme***

The Early Access to Medicines Scheme, or EAMS, applies in relation to patients with life threatening or seriously debilitating conditions and aims to give such patients access to unauthorized medicines, when there is a clear unmet medical need. Under EAMS, the MHRA will undertake a two-step evaluation process of a medicine, which includes a promising innovative medicine designation (an indication that a product may be eligible for EAMS based on early clinical data) and a scientific opinion on the risks and benefits of the medicine based on data gathered from the patients who will benefit from the medicine. A positive EAMS scientific opinion is valid for one year (which can be renewed) and regular updates must be provided to the MHRA following such positive opinion.

### ***Orphan Designation***

Since January 1, 2021, a separate process for orphan drug designation to the European Union process has applied Great Britain. There is now no pre-marketing authorization orphan designation (as there is in the European Union) in Great Britain and the application for orphan designation will be reviewed by the MHRA at the time of an application for a UK or Great Britain MA. The criteria for orphan designation remain the same as in the European Union, save that they apply to Great Britain only (e.g. there must be no satisfactory method of diagnosis, prevention or treatment of the condition concerned in Great Britain, as opposed to the European Union).

## **U.S. Data Privacy and Security Laws and Regulations**

We collect, store, transmit and process sensitive and confidential data and information, including health information, and personal data. As we seek to expand our business, we are, and will increasingly become, subject to numerous state, federal and foreign laws, regulations, rules and

government and industry standards relating to the collection, use, retention, security, disclosure, transfer and other processing of sensitive and personal information in the jurisdictions in which we operate. The regulatory framework for data privacy, data security and data transfers worldwide is rapidly evolving, and there has been an increasing focus on privacy and data protection issues.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of health information. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH Act), and their implementing regulations impose obligations on covered entities, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as business associates that provide services involving the use or disclosure of personal health information to or on behalf of covered entities. These obligations, such as mandatory contractual terms, relate to safeguarding the privacy and security of protected health information. Many states also have laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA. In addition, many states and foreign countries in which we operate have laws that protect the privacy and security of sensitive and personal information. Certain of these laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international or other state laws, and such laws may differ from each other.

### **Employees and human capital resources**

As of October 8, 2021, we had 42 full-time employees, of which eleven have M.D. (or its equivalent) Ph.D. or J.D. degrees. Within our workforce, 32 employees are engaged in research and development and ten are engaged in business development, finance, legal and general management and administration. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of equity-based compensation awards in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

### **Facilities**

Our corporate headquarters are located in Cambridge, Massachusetts, where we lease and occupy approximately 14,354 square feet of office space at 85 Bolton St, Cambridge, MA 02140. The current term of our Cambridge lease expires in July 2023.

We believe that our facilities are adequate for our current needs and for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space. We believe that suitable additional or substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations.

### **Legal proceedings**

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

## MANAGEMENT

### Executives and directors

The following table sets forth the name, age and position of each of our executives and directors as of October 1, 2021.

Name	Age	Position
<b>Executive Officers:</b>		
Elisabet de los Pinos, Ph.D.	48	Chief Executive Officer and Director
Julie Feder	51	Chief Financial Officer
Cadmus Rich, M.D.	56	Chief Medical Officer and Head of Research and Development
Mark De Rosch, Ph.D.	58	Chief Operating Officer
Christopher Primiano	41	Chief Business Officer
<b>Non-Employee Directors:</b>		
David Johnson(2)(3)	56	Chairman and Director
Giovanni Mariggi, Ph.D.(1)	36	Director
Antony Mattessich(1)(3)	54	Director
Raj Parekh, Ph.D.	61	Director
Sapna Srivastava, Ph.D.(1)	50	Director
Karan Takhar(2)(3)	30	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

Each executive officer serves at the discretion of our board of directors and holds office until his or her successor is duly elected and qualified or until his or her earlier resignation or removal. There are no family relationships among any of our directors or executive officers.

#### **Executive Officers**

**Elisabet de los Pinos, Ph.D.** is our founder and Chief Executive Officer. Since our founding in January 2010, Dr. de los Pinos has led our strategy and operations and has spearheaded our fundraising efforts. Prior to founding Aura, she was a brand manager in Eli Lilly & Co.'s oncology business unit, where she was part of the leadership team responsible for the market launch in Europe of Alimta, a drug for the treatment of lung cancer. Earlier in her career, Dr. de los Pinos worked as a post-doctoral fellow at the Institute of Cancer Research at the University of London. She previously completed research fellowships at the Mount Sinai School of Medicine Institute of Molecular Medicine of New York University and at the Georgetown School of Medicine. She is a member of the board of overseers at the Museum of Science, Boston. Dr. de los Pinos has been named to Boston Business Journal's 2009 "Top 40 under 40" list; as a Mass High Tech "Woman to Watch" in 2010; as a "Technology Pioneer" by the World Economic Forum in 2010; and as one of Goldman Sachs's "100 Most Intriguing Entrepreneurs" in 2014. Dr. de los Pinos holds a Ph.D., magna cum laude, in Molecular Biology from the University of Barcelona and an M.B.A. from IE Business School.

**Julie Feder** has served as our Chief Financial Officer since August 2018. Prior to this role, Ms. Feder served as Chief Financial Officer at Verastem Oncology, or Verastem, from July 2017 to June 2018, where she was responsible for developing the company's strategic financial plan and overseeing a rapid financial and staff growth. Prior to joining Verastem, Ms. Feder served as the Chief Financial Officer at the Clinton Health Access Initiative, Inc., or CHAI, from September 2011 to July 2017. At CHAI, Ms. Feder was responsible for managing a global team across multiple departments and developed the global finance strategy and internal audit, treasury and global payroll functions. Prior to joining CHAI, Ms. Feder spent three years at Genzyme Corporation, as Vice President of

Internal Audit and later as Finance Integration Leader. In these roles, she managed the day-to-day operations of Genzyme's global internal audit function, while leading the Genzyme Global Finance integration following Sanofi's acquisition of Genzyme. Ms. Feder began her career at Deloitte & Touche LLP, where she was Senior Manager of Audit, Consulting and Enterprise Risk Services. Ms. Feder holds a B.S. in Accounting from Yeshiva University's Sy Syms School of Business.

**Cadmus Rich, M.D., M.B.A.** has served as our Chief Medical Officer and Head of Research and Development since June 2019, having previously served as our Senior Vice President, Chief Medical Officer from October 2017 to May 2019. Before joining us, Dr. Rich was Vice President of Clinical Development and Medical Affairs at Inotek Pharmaceuticals from May 2015 to September 2017. He previously held several senior positions at Alcon Laboratories, Inc., or Alcon, including overseeing the pipeline strategy and R&D projects for Alcon's intraocular lens product line and leading global pharmaceutical clinical trial management. Dr. Rich has extensive experience in R&D, having led or participated in nearly 75 development programs, including the submission and approval of multiple devices and pharmaceutical products in the United States, European Union, China, Japan and Brazil/Latin America. He has directly led or participated in over 150 clinical trials across multiple ophthalmology and systemic indications as an executive leader, medical director, medical monitor and principal investigator. Dr. Rich has served on the board of directors of the North Carolina Specialty Hospital and is currently a member of the board of directors and treasurer of Prevent Blindness, the nation's longest-acting volunteer eye health and safety organization, and Sustained Nanosystems, LLC, a company developing extended release technologies for drugs. Dr. Rich holds an M.D. from the University of North Carolina at Chapel Hill School of Medicine, an M.B.A. from Regis University, a Certified Physician Executive Certification from the American Association for Physician Leadership and a B.A. in Psychology from Case Western Reserve University.

**Mark De Rosch, Ph.D.** has served as our Chief Operating Officer since March 2021. In this role, Dr. De Rosch is responsible for leading our global operations and regulatory strategy. Prior to joining us, Dr. De Rosch served as Chief Regulatory Officer of Epizyme, Inc., or Epizyme, from September 2019 to March 2021 and led regulatory efforts for their first approved product, TAZVERIK® (tazemetostat). Prior to Epizyme, Dr. De Rosch served as Senior Vice President, Regulatory Affairs and Quality Assurance for Nightstar Therapeutics, or Nightstar, (acquired by Biogen in 2019) from April 2018 to September 2019, where he developed and implemented global regulatory roadmaps for their gene therapy programs in choroideremia and retinitis pigmentosa. Prior to Nightstar, he served as Senior Vice President, Regulatory Affairs, Quality Assurance and Chemistry, Manufacturing and Controls at Akebia Therapeutics, Inc. from August 2014 to February 2018. Dr. De Rosch holds a Ph.D. and an M.S. in Inorganic Chemistry from the University of California, San Diego and a B.S. in Chemistry/Biochemistry from the University of Wisconsin-Parkside.

**Christopher Primiano** has served as our Chief Business Officer since September 2021. Prior to joining us, from March 2014 to December 2020, Mr. Primiano served in roles with increasing responsibility at Karyopharm Therapeutics, Inc., most recently as Executive Vice President, Chief Business Officer, General Counsel and Secretary. In this role, Mr. Primiano was responsible for leading Karyopharm's business development, operations and legal departments. Prior to joining Karyopharm, Mr. Primiano worked at multiple international law firms and led internal legal and business development departments. He was a counsel at Wilmer Cutler Pickering Hale and Dorr LLP, a full-service multinational law firm, and he served as Vice President, Corporate Development, General Counsel and Secretary of GlassHouse Technologies, Inc., an information technology consulting company, where he led global legal operations and managed asset and subsidiary acquisition and sale activity. Mr. Primiano began his career at Gunderson Dettmer Stough Villeneuve Franklin & Hachigian LLP, a global law firm focused on venture capital and the emerging technology marketplace. Mr. Primiano received an M.B.A. from the Boston College Carroll School of Management, a J.D. from Boston College Law School and a B.A. in Political Economy and English from Georgetown University.

**Non-employee directors**

**David Johnson** has served as a member of our board of directors since January 2021. Mr. Johnson has more than 25 years of experience in biopharmaceuticals and is currently the Chief Executive Officer of Solve Therapeutics, a biologics company focused on developing novel cancer therapeutics, which he founded in January 2021. Prior to founding Solve Therapeutics, Mr. Johnson founded VelosBio, an oncology-focused clinical stage biopharmaceutical company focused on novel antibody drug conjugates and bispecific antibodies, and served as the Chief Executive Officer from December 2017 to December 2020. While at VelosBio, Mr. Johnson raised approximately \$200 million in capital, and the company filed an IND for its lead ROR1-directed ADC VLS-101 in Q4 2018 and started enrolling patients in a Phase 1 first-in-human clinical trial in Q1 2019. In December 2020, VelosBio was acquired by Merck for \$2.75 billion. Prior to founding VelosBio, Mr. Johnson was the Chief Executive Officer at Acerta Pharma, or Acerta, from May 2013 to March 2016, where he led Acerta through a critical phase of growth from approximately 40 to over 150 employees and from a signal-seeking, first-in-human trial to more than 20 active clinical studies. His tenure included the regulatory negotiation and launch of three registration-directed trials, including two global Phase 3 trials for acalabrutinib. Mr. Johnson and his leadership team ultimately led the acquisition of Acerta by AstraZeneca in a deal valued at up to \$7 billion. Earlier in his career, Mr. Johnson served in roles spanning from pre-clinical development to all phases of clinical development through product launch. He has extensive experience in fundraising and deal making and has made significant contributions to drugs ultimately garnering NDA/sNDA approval, including acalabrutinib, idelalisib, romidepsin and bortezomib. Mr. Johnson has served on the board of directors of Zentalis Pharmaceuticals, Inc. (NASDAQ: ZNTL), or Zentalis, since January 2020. Mr. Johnson received a bachelor's degree in Economics from Indiana University. We believe that Mr. Johnson's experience as a pharmaceutical business leader provides him with the appropriate set of skills to serve as a member of our board of directors.

**Giovanni Mariggi, Ph.D.** has served as a member of our board of directors since April 2019. Dr. Mariggi is a member of the co-founding team at Medicxi, having served as a Partner since October 2018 and a Principal from February 2016 to September 2018. Prior to Medicxi, Dr. Mariggi served in multiple roles at Index Ventures, or Index, over four years, ultimately serving as a Principal from January 2015 to January 2016. Prior to joining Index, Dr. Mariggi worked at Cancer Research UK's London Research Institute (now the Crick Institute) conducting research on vascular biology and angiogenesis, whilst also performing competitive intelligence projects as an independent consultant to various biopharma companies. He currently serves on the boards of a number of portfolio companies, including Gadeta B.V. Dr. Mariggi holds a Ph.D. in Biochemistry and Molecular Biology from University College London and a B.Sc. in Biochemistry from Imperial College London. We believe Dr. Mariggi's experience and background in the biopharmaceutical industry provides him with the appropriate set of skills to serve as a member of our board of directors.

**Antony Mattessich** has served as a member of our board of directors since September 2021. Mr. Mattessich is currently the Chief Executive Officer of Ocular Therapeutix, a position he has held since August 2017. Prior to Ocular Therapeutix, beginning in 2009, he served in roles of increasing responsibility at Mundipharma International, including serving as Managing Director from May 2011 to August 2017. Previous to his time at Mundipharma, Mr. Mattessich ran the U.S. respiratory, dermatology and pediatrics group at Novartis AG, or Novartis. Before Novartis, Mr. Mattessich held several positions at Bristol-Myers Squibb, among them, Managing Director roles in Malaysia/Singapore and The Netherlands, and Head of Operations for the International Medicines Group. Mr. Mattessich holds a Masters in International Affairs from Columbia University and a B.A. from the University of California at Berkeley. We believe Mr. Mattessich's leadership experience in biotech and pharmaceuticals provides him with the appropriate set of skills to serve as a member of our board of directors.

**Raj Parekh, Ph.D.** has served as a member of our board of directors since 2015. Dr. Parekh joined Advent Life Sciences as a General Partner in 2005, bringing over 20 years of experience in biomedical research and as an entrepreneur and investor. Since joining Advent, he has been involved with portfolio companies primarily engaged in the discovery of new medicines, including Avila Therapeutics, Inc., EUSA Pharma, Inc. and Thiakis Limited. Earlier in his career, Dr. Parekh co-founded Oxford GlycoSciences, which was sold to UCB-Celltech, and then served as Chairman of Galapagos NV, a member of the Supervisory Board of the Novartis Venture Fund and a founding director of Celldex Therapeutics. Dr. Parekh currently serves on the boards of directors of several portfolio companies, including Arrakis and Levicept. Dr. Parekh holds a Ph.D. in Molecular Medicine and an M.A. in Biochemistry from Oxford University. We believe Dr. Parekh's experience and background provides him with the appropriate set of skills to serve as a member of our board of directors.

**Sapna Srivastava, Ph.D.** has served as a member of our board of directors since May 2021. Dr. Srivastava most recently served as the Chief Financial Officer at eGenesis, Inc., or eGenesis, a position she has held from March 2021 until October 2021. Prior to eGenesis, she held similar roles as the Chief Financial and Strategy Officer at Abide Therapeutics, Inc. (acquired by Lundbeck) from September 2017 to January 2019 and at Intellia Therapeutics, Inc., or Intellia, from April 2015 to December 2016. In these positions, she has played a key role in equity financings including a successful initial public offering, strategic alliances, mergers and acquisitions and shaping the strategic direction of the companies. Before Intellia, Dr. Srivastava spent more than a decade as a senior biotechnology analyst for Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC and ThinkEquity Partners. She has served on the board of VelosBio Inc., and currently serves on the boards of directors for Talaris Therapeutics, Inc. (NASDAQ: TALS), Nuvalent, Inc. (NASDAQ: NUVL), SQZ Biotechnologies Company (NASDAQ: SQZ) and Social Capital Suvretta Holdings Corp. II (NASDAQ: DNAB), a special purpose acquisition corporation. Dr. Srivastava holds a Ph.D. in Neuroscience from the New York University School of Medicine and a B.S. in Microbiology from St. Xavier's College at the University of Mumbai. We believe Dr. Srivastava's experience as an executive officer in the biopharmaceutical industry and investment banking provides her with the appropriate set of skills to serve as a member of our board of directors.

**Karan Takhar** has served as a member of our board of directors since March 2021. Since 2013, Mr. Takhar has held roles of increasing responsibility at Matrix Capital Management, L.P., or Matrix, an investment fund focused on technology and life sciences. He currently serves as a Senior Managing Director and the head of Life Sciences investing, a position he has held since February 2021. He previously served as a Managing Director from January 2017 to January 2021 and as a Vice President from January 2016 to December 2016. Mr. Takhar has served as a member of the board of directors of Zentalis since December 2017. Mr. Takhar received a B.S. in Economics and Mathematics from the Massachusetts Institute of Technology. We believe Mr. Takhar's experience investing in life sciences companies provides him with the appropriate set of skills to serve as a member of our board of directors.

#### **Composition of our board of directors**

Our board consists of six members, each of whom are members pursuant to the board composition provisions of our certificate of incorporation and agreements with our stockholders, and is chaired by Mr. Johnson. These board composition provisions will terminate upon the completion of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance committee's and our board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business,



understanding of the competitive landscape, professional and personal experiences, and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our tenth amended and restated certificate of incorporation that will become effective upon the closing of this offering and amended and restated bylaws that became effective upon the effectiveness of the registration statement of which this prospectus is a part, also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

***Director independence***

Our common stock has been approved for listing on the Nasdaq Global Market. Under the Nasdaq listing rules, independent directors must comprise a majority of a listed company's board of directors within twelve months from the date of listing. In addition, the Nasdaq listing rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent within twelve months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under Nasdaq listing rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (2) be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board of directors must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

Our board of directors has determined that all members of the board of directors, except Dr. de los Pinos, are independent directors, including for purposes of the rules of The Nasdaq Global Market and the SEC. In making such independence determinations, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock. Upon the completion of this offering, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of The Nasdaq Global Market and the rules and regulations of the SEC. There are no family relationships among any of our directors or executive officers. Dr. de los Pinos is not an independent director under these rules because she is our President and Chief Executive Officer.

***Staggered board***

In accordance with the terms of our tenth amended and restated certificate of incorporation that will become effective upon the closing of this offering and amended and restated bylaws that became upon

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the effectiveness of the registration statement of which this prospectus is a part, our board of directors will be divided into three staggered classes of directors and each will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2022 for Class I directors, 2023 for Class II directors and 2024 for Class III directors.

- Our Class I directors will be Giovanni Mariggi, Raj Parekh and Elisabet de los Pinos;
- Our Class II directors will be David Johnson and Karan Takhar; and
- Our Class III directors will be Sapna Srivastava and Antony Mattessich.

Our tenth amended and restated certificate of incorporation that will become effective upon the closing of this offering and amended and restated by-laws that became effective upon the effectiveness of the registration statement of which this prospectus is a part provide that the number of our directors shall be fixed from time to time by a resolution of the majority of our board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

### **Board leadership structure and board's role in risk oversight**

Currently, the role of chairman of our board of directors is separated from the role of Chief Executive Officer. Our Chief Executive Officer is responsible for recommending strategic decisions and capital allocation to the board of directors and to ensure the execution of the recommended plans. The chairman of our board of directors is responsible for leading the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that the Chief Executive Officer is required to devote to her position in the current business environment, as well as the commitment required to serve as our chairman, particularly as the board of directors' oversight responsibilities continue to grow. While our amended and restated by-laws and corporate governance guidelines will not require that our chairman and Chief Executive Officer positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including the four risks more fully discussed in the section entitled "Business" appearing elsewhere in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees below and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairman of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

## **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, each of which operate pursuant to a charter adopted by our board of directors and that became effective upon the effectiveness of the registration statement of which this prospectus is a part. The board of directors may also establish other committees from time to time to assist us and our board of directors. The composition and functioning of all of our committees complies with all applicable requirements of the Sarbanes-Oxley Act of 2002, Nasdaq and SEC rules and regulations, if applicable. Each committee's charter will be available on our website at [www.aurabiosciences.com](http://www.aurabiosciences.com). The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be part of this prospectus.

### ***Audit committee***

Sapna Srivastava, Giovanni Mariggi and Antony Mattessich serve on the audit committee, which is chaired by Sapna Srivastava. Our board of directors has determined that each are "independent" for audit committee purposes as that term is defined by the rules of the SEC and Nasdaq, and that each has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has determined that Sapna Srivastava qualifies as an "audit committee financial expert," as defined under the applicable rules of the SEC. The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of, our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending, based upon the audit committee's review and discussions with management and our independent registered public accounting firm, whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

### ***Compensation committee***

David Johnson and Karan Takhar serve on the compensation committee, which is chaired by David Johnson. Our board of directors has determined that each member of the compensation committee is "independent" as defined in the applicable Nasdaq rules. The compensation committee's responsibilities include:

- annually reviewing and determining the corporate goals and objectives relevant to the compensation of our Chief Executive Officer;

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- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and, based on such evaluation, determining the cash compensation of our Chief Executive Officer;
- determining the cash compensation of our other executive officers;
- overseeing and administering our compensation and similar plans;
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters and evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- retaining and approving the compensation of any compensation advisors;
- reviewing and approving the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors; and
- preparing the compensation committee report required by SEC rules, if and when required, to be included in our annual proxy statement.

Each member of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code.

### ***Nominating and corporate governance committee***

Antony Mattessich, David Johnson and Karan Takhar serve on the nominating and corporate governance committee, which is chaired by Antony Mattessich. Our board of directors has determined that a majority of the nominating and corporate governance committee is "independent" as defined in the applicable Nasdaq rules. The nominating and corporate governance committee's responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- reviewing and recommending to the board of directors appropriate corporate governance guidelines; and
- overseeing the evaluation of our board of directors.

Our board of directors may from time to time establish other committees.

### **Compensation committee interlocks and insider participation**

In 2020, the compensation committee consisted of George Golumbeski, Giovanni Mariggi, and Arthur Pappas. None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

### **Code of Business Conduct and Ethics**

Our board of directors adopted a Code of Business Conduct and Ethics in connection with this offering. The Code of Business Conduct and Ethics applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer, or controller, or persons performing similar functions. Upon the completion of this offering, the full text of our Code of Business Conduct and Ethics will be posted on our website at [www.aurabiosciences.com](http://www.aurabiosciences.com). The information on our website is deemed not to be incorporated in this prospectus or to be a part of this prospectus. If we make any substantive amendments to, or grant any waivers from, our Code of Business Conduct and Ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

### **Limitations on Liability and Indemnification Agreements**

As permitted by Delaware law, provisions in our tenth amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, and amended and restated bylaws, which became effective upon the effectiveness of this registration statement, limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, a director exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter a director's liability under other laws, such as the federal securities laws or other state or federal laws. Our tenth amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated bylaws will also 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 connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

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In addition to the indemnification that will be provided for in our tenth amended and restated certificate of incorporation and is provided for in our amended and restated bylaws, we plan to enter into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our tenth amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

**EXECUTIVE COMPENSATION**

The following discussion contains forward looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. The actual amount and form of compensation and the compensation policies and practices that we adopt in the future may differ materially from currently planned programs as summarized in this discussion.

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to “smaller reporting companies,” as such term is defined in the rules promulgated under the Securities Act. The compensation provided to our named executive officers for the fiscal year ended December 31, 2020 is detailed in the 2020 Summary Compensation Table and accompanying footnotes and narrative that follow. Our named executive officers are:

- Elisabet de los Pinos, Ph.D, our Chief Executive Officer;
- Julie Feder, our Chief Financial Officer; and
- Cadmus Rich, M.D., our Chief Medical Officer and Head of Research and Development.

To date, the compensation of our named executive officers has consisted of a combination of base salary, cash bonuses and long-term incentive compensation in the form of stock options. Our named executive officers, like all full-time employees, are eligible to participate in our health and welfare benefit plans. As we transition from a private company to a publicly traded company, we intend to evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require.

**2020 Summary Compensation Table**

The following table shows the total compensation earned by, or paid to, our named executive officers for services rendered to us in all capacities during the fiscal year ended December 31, 2020.

<u>Name and principal position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus \$(1)</u>	<u>Option Awards \$(2)</u>	<u>Non-Equity Incentive Plan Compensation (\$)</u>	<u>All Other Compensation \$(3)</u>	<u>Total (\$)</u>
Elisabet de los Pinos, Ph.D. <i>Chief Executive Officer</i>	2020	394,890	148,913	533,997	–	17,100	1,094,900
Julie Feder <i>Chief Financial Officer</i>	2020	343,216	113,249	95,877	–	–	552,342
Cadmus Rich, M.D. <i>Chief Medical Officer and Head of Research and Development</i>	2020	377,280	124,488	113,498	–	17,100	632,366

(1) Amounts represent discretionary cash bonuses paid to our named executive officers based on performance in 2020.

(2) Amounts represent the aggregate grant date fair value of the option awards granted to our named executive officers during our fiscal year ended December 31, 2020, computed in accordance with FASB ASC Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in Note 9 to our financial statements for the year ended December 31, 2020, included elsewhere in this prospectus. This amount does not correspond to the actual value that may be recognized by the named executive officer upon exercise of the applicable award or sale of the underlying shares of stock.

(3) The amounts reported represent matching contributions made by the Company under the Company's 401(k) plan.

#### **Narrative Disclosure to Summary Compensation Table**

##### ***2020 salaries***

Our named executive officers each receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Base salaries are reviewed annually, typically in connection with our annual performance review process, approved by our board of directors or the compensation committee, and may be adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance, and experience.

For fiscal year 2020, the annual base salary for each of Dr. de los Pinos, Ms. Feder and Dr. Rich were \$391,875, \$340,596 and \$374,400, respectively.

##### ***2020 bonuses***

For the fiscal year ended December 31, 2020, each of our named executive officers was eligible to earn an annual cash bonus based on performance as determined at the discretion of our board of directors. The target annual bonuses for Dr. de los Pinos, Ms. Feder and Dr. Rich for the fiscal year ended December 31, 2020 were 40%, 35% and 35% of annual base salary, respectively. The discretionary cash bonus paid to each named executive officer with respect to the fiscal year ended December 31, 2020 is reported in the "Bonus" column of the "2020 Summary Compensation Table" above.

##### ***Equity-based compensation***

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants promote executive retention because they incentivize our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors or our compensation committee periodically review the equity incentive compensation of our named executive officers and may grant equity incentive awards to them from time to time. In March 2020, we granted Dr. de los Pinos, Ms. Feder and Dr. Rich options to purchase 194,889, 34,990 and 41,422 shares of our common stock, respectively, with an exercise price per share equal to the fair market value of our common stock on the date of grant.



**Outstanding Equity Awards at 2020 Fiscal Year End**

The following table lists all outstanding equity awards held by our named executive officers as of December 31, 2020.

Name	Option Awards(1)			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Elisabet de los Pinos, Ph.D.	3,649	—	5.48	10/28/2021
	5,474	—	5.75	10/1/2024
	10,948	—	5.07	6/2/2025
	14,598	—	5.48	4/11/2026
	13,379	1,219(2)	5.21	7/7/2027
	258,514	106,449(3)	2.74	2/21/2028
	29,125	34,423(4)	3.15	2/6/2029
	40,601	154,288(5)	4.25	3/15/2030
Julie Feder	52,299	37,358(6)	2.74	10/3/2028
	8,363	9,885(5)	3.15	2/6/2029
	7,289	27,701(7)	4.25	3/15/2030
Cadmus Rich, M.D.	23,114	6,083(8)	5.21	10/11/2027
	56,872	23,419(9)	2.74	2/21/2028
	8,363	9,885(3)	3.15	2/6/2029
	8,629	32,793(5)	4.25	3/15/2030

- (1) Each of the outstanding equity awards in the table above was granted pursuant to our Amended and Restated 2009 Stock Incentive Plan, as amended, or the 2009 Plan, or our 2018 Equity Incentive Plan, as amended, or the 2018 Plan.
- (2) The shares underlying this option vest in 48 monthly installments, equal to 2.0833% of the shares, over the 48 months following April 12, 2017.
- (3) The shares underlying this option vest in 48 monthly installments, equal to 2.0833% of the shares, over the 48 months following February 21, 2018.
- (4) The shares underlying this option vest in 48 monthly installments, equal to 2.0833% of the shares, over the 48 months following February 6, 2019. If the executive's employment is terminated without "cause" (as defined in the 2018 Plan) within 12 months following a "change of control" (as defined in the applicable option award agreement) all unvested shares will immediately accelerate and vest.
- (5) The shares underlying this option vest in 48 monthly installments, equal to 2.0833% of the shares, over the 48 months following February 6, 2020.
- (6) The shares underlying this option vest as follows: 25% of the shares vest on the first anniversary of August 13, 2018 with the remainder vesting thereafter pro-rata in 36 monthly installments.
- (7) The shares underlying this option vest as follows: 25% of the shares vest on the first anniversary of February 6, 2019 with the remainder vesting thereafter pro-rata in 36 monthly installments. If the executive's employment is terminated without "cause" (as defined in the 2018 Plan) within 12 months following a "change of control" (as defined in the applicable option award agreement) all unvested shares will immediately accelerate and vest.
- (8) The shares underlying this option vest as follows: 25% of the shares vest on the first anniversary of October 23, 2017 with the remainder vesting thereafter pro-rata in 36 monthly installments.
- (9) The shares underlying this option vest as follows: 25% of the shares vest on the first anniversary of February 21, 2018 with the remainder vesting thereafter pro-rata in 36 monthly installments.

## **Executive Compensation Arrangements**

### ***Employment Arrangements in Place Prior to the Offering for Named Executive Officers***

#### ***Elisabet de los Pinos, Ph.D.***

We entered into an employment agreement with Dr. de los Pinos, who serves as our Chief Executive Officer, in January 2015, which we amended in October 2017, or as amended, the de los Pinos Employment Agreement. The de los Pinos Employment Agreement provides for Dr. de los Pinos's at-will employment, base salary and annual target bonus. Dr. de los Pinos is also eligible to participate in the employee benefit plans available to our employees, subject to the terms of those plans.

Pursuant to the de los Pinos Employment Agreement, in the event that Dr. de los Pinos's employment is terminated by us without "cause" or by Dr. de los Pinos for "good reason" (as defined in the de los Pinos Employment Agreement), subject to the execution and effectiveness of a release within 60 days of such termination, she will be entitled to receive (i) 12 months of base salary continuation and a pro-rata share of any bonus for which Dr. de los Pinos was eligible, (ii) continued vesting of stock options for 12 months and (iii) subject to the Dr. de los Pinos's timely election to continue COBRA health coverage and copayment of premium amounts at the applicable active employees' rate, we will continue to pay the share of the premiums that we would have paid to provide health insurance to Dr. de los Pinos for the 12 month severance period. In the event that such termination occurs within nine months after a "change of control" (as defined in the de los Pinos Employment Agreement), Dr. de los Pinos will, subject to the execution and effectiveness of a release within 60 days of such termination, be entitled to receive a lump sum payment equal to 12 months of base salary as of the date of termination.

The de los Pinos Employment Agreement contains non-competition and non-solicitation provisions that apply during Dr. de los Pinos's employment with us and for one year thereafter.

#### ***Julie B. Feder***

In August 2018, we entered into an employment offer letter, or the Feder Offer Letter, with Ms. Feder who serves as our Chief Financial Officer. The Feder Offer Letter provides for Ms. Feder's at-will employment, base salary and target annual bonus. Ms. Feder is eligible to participate in the employee benefit plans available to our employees, subject to the terms of those plans.

Pursuant to the Feder Offer Letter, in the event that Ms. Feder's employment is terminated by us without "cause" (as defined in the Feder Offer Letter), subject to her execution of a release within 60 days of such termination, Ms. Feder will be entitled to (i) continuation of her base salary for nine months and (ii) provided Ms. Feder has properly elected to continue her healthcare coverage pursuant to COBRA, the continuation of healthcare coverage premiums on the same premium-sharing basis for nine months.

Ms. Feder has also entered into a Confidential Information, Non-Solicitation and Invention Assignment Agreement with us that contains non-disclosure provisions that apply during and for 12 months following her employment with us.

#### ***Cadmus Rich, M.D.***

In October 2017, we entered into an employment offer letter, or the Rich Offer Letter, with Dr. Rich, who serves as our Senior Vice President and Chief Medical Officer. The Rich Offer Letter provides for Dr. Rich's at-will employment, base salary and target annual bonus. Dr. Rich is eligible to participate in the employee benefit plans available to our employees, subject to the terms of those plans.

Pursuant to the Rich Offer Letter, in the event that Dr. Rich's employment is terminated by us without "cause" (as defined in the Rich Offer Letter), subject to his execution of a release within 60 days of such termination, he will be entitled to receive (i) continuation of his annual base salary for nine months and (ii) subject to Dr. Rich's timely election to continue COBRA health coverage and

copayment of premium amounts at the applicable active employees' rate, a monthly cash payment equal to the amount that we would have paid to provide health insurance to Dr. Rich for nine months.

Dr. Rich has also entered into an Confidentiality, Intellectual Property, Non-Competition and Non-Solicitation Agreement with us that contains non-competition and non-disclosure provisions that apply during and for one year following his employment with us.

***Equity Grants to Certain Employees in Connection with Our Initial Public Offering***

In October 2021, our board of directors approved an equity grant to each of our named executive officers in connection with our initial public offering. These equity awards were granted upon the effectiveness of the registration statement of which this prospectus forms a part and with an exercise price equal to the initial public offering price per share. These awards were granted under our 2021 Plan.

Dr. de los Pinos will receive a grant of 318,750 stock options and 74,357 RSUs. Each of Ms. Feder and Dr. Rich will receive a grant of 112,500 stock options and 26,250 RSUs. The stock options will vest and become exercisable as follows: 25% of the shares subject to the stock option shall vest on the first anniversary of the vesting commencement date and the remaining 75% of the shares subject to the stock option shall vest in 36 equal monthly installments thereafter, subject to such executive officer's continued service to us through each applicable vesting date. The RSUs will vest as follows: 25% of the RSUs shall vest on each anniversary of the vesting commencement date over four years, subject to such employee's continued service to us through each applicable vesting date.

**Employee Benefit and Equity Compensation Plans**

***Amended and Restated 2009 Stock Option and Restricted Stock Plan***

Our 2009 Plan was adopted by our board of directors on January 15, 2009, approved by our stockholders on January 16, 2009, and most recently amended in September 2018. Under the 2009 Plan, we reserved for issuance an aggregate of 1,263,605 shares of our common stock. The number of shares of common stock reserved for issuance shall be equitably adjusted by the our board of directors in the event of any merger, consolidation, sale of all or substantially all of our assets, reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in capitalization or event.

Following the adoption of our 2018 Plan, no awards have been granted under the 2009 Plan and the shares of common stock underlying awards under the 2009 Plan that are terminated, surrendered or cancelled are forfeited in whole or in part or otherwise result in shares of common stock not being issued are currently added to the shares of common stock available for issuance under the 2018 Plan. Following this offering, such shares will be added to the shares of common stock available for issuance under the 2021 Plan.

Our board of directors has acted as administrator of the 2009 Plan. The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, and to determine the specific terms and conditions of each award, subject to the provisions of the 2009 Plan. Persons eligible to participate in the 2009 Plan are employees, officers and directors of, and consultants and advisors to, our company as selected from time to time by the administrator in its discretion.

The 2009 Plan permits the granting of (1) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended, or the Code, and (2) options that do not so qualify. The per share exercise price of each option is determined by our board of directors but may not be less than 100% of the fair market value of the common stock

on the date of grant. The term of each option is fixed by our board of directors but may not exceed ten years from the date of grant. Our board of directors determines at what time or times each option may be exercised.

In addition, the 2009 Plan permits the granting of restricted shares of common stock.

The 2009 Plan provides that upon the expectation of the occurrence of a “acquisition event,” as defined in the 2009 Plan, (i) all then unvested outstanding options shall terminate immediately prior to the consummation of such acquisition event, and (ii) the administrator shall take any one or more or none of the following actions with respect to all then vested outstanding options: (a) provide that such vested outstanding options shall be assumed or equivalent options shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof); (b) upon written notice to the optionees, provide that all then vested outstanding options will terminate immediately prior to the consummation of the acquisition event, except to the extent exercised by the optionee prior to the consummation; (c) in the event of a merger under the terms of which holders of common stock will receive a cash or stock payment for each share surrendered in the merger, the “merger price,” provide for a cash or stock payment to each optionee equal to (A) the merger price, times the number of shares of common stock issuable to that optionee upon the exercise by that optionee of such of that optionee’s vested outstanding options which the optionee actually elects to exercise less (B) the aggregate exercise price of all such outstanding options which the optionee actually exercises in exchange for the termination of all outstanding options; (d) terminate each such vested outstanding option in exchange for a cash payment equal to the amount by which the value of the common stock issuable upon exercise exceeds the exercise price with respect to such common stock; or (e) provide for a combination of any one or more of the foregoing options or any other plan which would be equitable in the good faith judgment of the administrator.

The board of directors may amend or discontinue the 2009 Plan at any time, subject to stockholder approval where such approval is required by applicable law. The administrator of the 2009 Plan may also amend or cancel any outstanding award, provided that no amendment to an award may materially adversely affect a participant’s rights without his or her consent. The administrator of the 2009 Plan is specifically authorized to exercise its discretion to reduce the exercise price of outstanding awards or effect the repricing of such awards through cancellation and re-grants.

The 2009 Plan terminated on the day prior to the tenth anniversary of the date of its adoption.

#### ***2018 Equity Incentive Plan***

The 2018 Plan was adopted by our board of directors on December 12, 2018, approved by our stockholders on December 12, 2018. Under the 2018 Plan, we have reserved for issuance an aggregate number of shares equal to the sum of (i) 4,017,100 shares of our common stock and (ii) any shares of common stock underlying awards granted under the 2009 Plan that are forfeited, expire or are cancelled without delivery of shares after December 12, 2018. The number of shares of common stock reserved for issuance shall be equitably adjusted by the our board of directors in the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event.

The shares of common stock underlying awards that are terminated, surrendered or cancelled, are forfeited in whole or in part or otherwise result in shares of common stock not being issued are currently added back to the shares of common stock available for issuance under the 2018 Plan. Following this offering, such shares will be added to the shares of common stock available for issuance under the 2021 Plan.

Our board of directors has acted as administrator of the 2018 Plan. The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be

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granted, and to determine the specific terms and conditions of each award, subject to the provisions of the 2018 Plan. Persons eligible to participate in the 2018 Plan are employees, directors of, and consultants to, our company or its affiliates, as selected from time to time by the administrator in its discretion.

The 2018 Plan permits the granting of (1) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended, or the Code, and (2) options that do not so qualify. The per share exercise price of each option is determined by our board of directors but may not be less than 100% of the fair market value of the common stock on the date of grant. The term of each option is fixed by our board of directors but may not exceed 10 years from the date of grant. Our board of directors determines at what time or times each option may be exercised.

In addition, the 2018 Plan permits the granting of restricted shares of common stock.

The 2018 Plan provides that upon the occurrence of a “corporate transaction,” as defined in the 2018 Plan, the administrator shall, as to outstanding options, either (i) make appropriate provisions for the continuation of such options by such options by substituting on an equitable basis for the shares then subject to such options either the consideration payable with respect to the outstanding shares of common stock in connection with the corporate transaction or securities of any successor or acquiring entity; or (ii) upon written notice to the participants, provide that such options must be exercised (either to the extent then exercisable or, at the discretion of the administrator, any such options being made partially or fully exercisable), within a specified number of days of the date of such notice, at the end of which period such options which have not been exercised shall terminate; or (iii) terminate such options in exchange for payment of an amount equal to the consideration payable upon consummation of such corporate transaction to a holder of the number of shares of common stock into which such option would have been exercisable (either to the extent then exercisable, or, at the discretion of the administrator, any such options being made partially or fully exercisable) less the aggregate exercise price thereof. With respect to any grants of restricted stock, the administrator shall provide for the continuation or substitution of such awards or provide for the termination of such awards in exchange for the payment of consideration equal to the consideration payable upon consummation of the transaction to a holder of the number of shares of common stock underlying such award (to the extent no longer subject to forfeiture or repurchase or, at the administrator’s discretion, with all forfeiture and repurchase rights being waived in the corporate transaction).

The board of directors may amend or discontinue the 2018 Plan at any time, subject to stockholder approval where such approval is required by applicable law. The administrator of the 2018 Plan may also amend or cancel any outstanding award, provided that no amendment to an award may materially adversely affect a participant’s rights without his or her consent. The administrator of the 2018 Plan is specifically authorized to exercise its discretion to reduce the exercise price of outstanding awards or effect the repricing of such awards through cancellation and re-grants.

The 2018 Plan will automatically terminate upon the earlier of ten years from the date on which the 2018 Plan was initially adopted by our board of directors or ten years from the date the 2018 Plan was initially approved by our stockholders. As of October 15, 2021, options to purchase 3,161,301 shares of common stock were outstanding under the 2018 Plan. Our board of directors has determined not to make any further awards under the 2018 Plan following the closing of this offering.

### ***2021 Stock Option and Incentive Plan***

The 2021 Plan was adopted by our board of directors on October 7, 2021, approved by our stockholders on October 22, 2021 and will become effective upon the date immediately preceding the date on which the registration statement of which this prospectus is part is declared effective by the SEC. The 2021 Plan will replace the 2018 Plan as our board of directors has determined not to make

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additional awards under the 2018 Plan following the closing of our initial public offering. However, the 2018 Plan will continue to govern outstanding equity awards granted thereunder. The 2021 Plan allows us to make equity-based and cash-based incentive awards to our officers, employees, directors and consultants.

We have initially reserved 3,352,166 shares of our common stock for the issuance of awards under the 2021 Plan, or the Initial Limit. The 2021 Plan provides that the number of shares reserved and available for issuance under the 2021 Plan will automatically increase on January 1, 2022 and each January 1 thereafter, by 5% of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation committee, or the Annual Increase. The number of shares reserved under the 2021 Plan subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares we issue under the 2021 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards under the 2021 Plan, the 2018 Plan and the 2009 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2021 Plan.

The maximum number of shares of common stock that may be issued in the form of incentive stock options shall not exceed the Initial Limit, cumulatively increased on January 1, 2022 and on each January 1 thereafter by the lesser of the Annual Increase for such year or 3,352,166 shares of common stock.

The grant date fair value of all awards made under our 2021 Plan and all other cash compensation paid by us to any non-employee director in any calendar year for services as a non-employee director shall not exceed \$750,000; provided, however, that such amount shall be \$1,000,000 for the calendar year in which the applicable non-employee director is initially elected or appointed to the board of directors.

The 2021 Plan will be administered by our compensation committee. Our compensation committee has the full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted and the number of shares subject to such awards, to make any combination of awards to participants, to accelerate at any time the exercisability or vesting of any award and to determine the specific terms and conditions of each award, subject to the provisions of the 2021 Plan. Persons eligible to participate in the 2021 Plan will be those full or part-time officers, employees, non-employee directors and consultants as selected from time to time by our compensation committee in its discretion.

The 2021 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant unless the option is granted (i) pursuant to a transaction described in, and in a manner consistent with Section 424(a) of the Code or (ii) to individuals who are not subject to U.S. income tax. The term of each option will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights under the 2021 Plan subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the

exercise price. The exercise price of each stock appreciation right may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Our compensation committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. Our compensation committee may also grant shares of common stock that are free from any restrictions under the 2021 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock.

Our compensation committee may grant cash bonuses under the 2021 Plan to participants, subject to the achievement of certain performance goals.

The 2021 Plan provides that upon the effectiveness of a “sale event,” as defined in the 2021 Plan, an acquirer or successor entity may assume, continue or substitute outstanding awards under the 2021 Plan. To the extent that awards granted under the 2021 Plan are not assumed or continued or substituted by the successor entity, upon the effective time of the sale event, such awards shall terminate. In such case, except as may be otherwise provided in the relevant award certificate, all awards with time-based vesting, conditions or restrictions shall become fully vested and nonforfeitable as of the effective time of the sale event and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in connection with a sale event in the administrator’s discretion or to the extent specified in the relevant award certificate. In the event of such termination, (i) individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) within a specified period of time prior to the sale event or (ii) we may make or provide for a payment, in cash or in kind, to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights and we may make or provide for a payment, in cash or in kind, to participants holding other vested awards.

Our board of directors may amend or discontinue the 2021 Plan and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder’s consent. Certain amendments to the 2021 Plan require the approval of our stockholders. The administrator of the 2021 Plan is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants without stockholder consent. No awards may be granted under the 2021 Plan after the date that is ten years from the effective date of the 2021 Plan. No awards under the 2021 Plan have been made prior to the date of this prospectus.

#### ***2021 Employee Stock Purchase Plan***

The ESPP was adopted by our board of directors on October 7, 2021, approved by our stockholders on October 22, 2021 and will become effective on the date immediately preceding the date on which the registration statement of which this prospectus forms a part is declared effective by the SEC. The ESPP is intended to qualify as an “employee stock purchase plan” within the meaning of

Section 423 of the Code. The ESPP initially reserves and authorizes the issuance of up to a total of 335,217 shares of our common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2022 and each January 1 thereafter through January 1, 2031, by the least of (i) 335,217 shares of our common stock, (ii) 1% of the outstanding number of shares of common stock on the immediately preceding December 31 or (iii) such lesser number of shares of common stock as determined by the administrator of the ESPP. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

All employees who are customarily employed by us or one of our designated subsidiaries for more than 20 hours per week and who we have employed for at least 30 days are eligible to participate in the ESPP. However, any employee who owns 5% or more of the total combined voting power or value of all classes of our stock will not be eligible to purchase shares of common stock under the ESPP.

We may make one or more offerings each year to our employees to purchase shares under the ESPP. Offerings will usually begin on such dates as determined by the compensation committee and will continue for six-month periods, referred to as offering periods. Each eligible employee may elect to participate in any offering by submitting an enrollment form at least 15 business days before the applicable offering date.

Each employee who is a participant in the ESPP may purchase shares of our common stock by authorizing payroll deductions of up to 15% of his or her eligible compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares of our common stock on the last business day of the offering period at a price equal to 85% of the fair market value of the shares of our common stock on the first business day or the last business day of the offering period, whichever is lower, provided that no more than \$25,000 worth of common stock (or such other lesser maximum number of shares as may be established by the administrator) may be purchased by any one employee during any offering period. Under applicable tax rules, an employee may purchase no more than \$25,000 worth of shares of our common stock, valued at the start of the purchase period, under the ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

The ESPP may be terminated or amended by our board of directors at any time. An amendment that increases the number of shares of our common stock authorized under the ESPP and certain other amendments require the approval of our stockholders.

#### ***Senior Executive Cash Incentive Bonus Plan***

On October 7, 2021 our board of directors adopted the Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan. The Bonus Plan provides for annual cash bonus payments based upon the attainment of company and individual performance targets established by our compensation committee. The payment targets will be related to financial and operational measures or objectives with respect to our company, or the Corporate Performance Goals, as well as individual performance objectives.

Our compensation committee may select Corporate Performance Goals from among the following: research and development, publication, clinical and/or regulatory milestones; cash flow (including, but not limited to, operating cash flow and free cash flow); revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes,



depreciation and/or amortization); changes in the market price of our common stock; economic value-added; acquisitions or strategic transactions, including collaborations, joint ventures or promotion arrangements; operating income (loss); return on capital assets, equity, or investment; stockholder returns; return on sales; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of our common stock; bookings, new bookings or renewals; sales or market shares; number of customers, number of new customers or customer references; operating income and/or net annual recurring revenue; or any other performance goal as selected by the compensation committee, any of which may be measured in absolute terms, as compared to any incremental increase, in terms of growth, as compared to results of a peer group, against the market as a whole, compared to applicable market indices and/or measured on a pre-tax or post-tax basis.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The Corporate Performance Goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the Corporate Performance Goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period, but no later than 74 days after the end of the fiscal year in which such performance period ends. Subject to the rights contained in any agreement between the executive officer and us, an executive officer must be employed by us on the bonus payment date to be eligible to receive a bonus payment. The Bonus Plan also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion.

#### ***401(k) plan***

We currently maintain a 401(k) retirement savings plan for our employees, including our named executive officers, who satisfy certain eligibility requirements. Our named executive officers are eligible to participate in the 401(k) plan on the same terms as other full-time employees. Our 401(k) plan is intended to qualify for favorable tax treatment under Section 401(a) of the Code, and contains a cash or deferred feature that is intended to meet the requirements of Section 401(k) of the Code. We believe that providing a vehicle for tax-deferred retirement savings through our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies.

## NON-EMPLOYEE DIRECTOR COMPENSATION

The following table presents the total compensation for each person who served as a non-employee member of our board of directors during the year ended December 31, 2020. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2020. We reimburse non-employee members of our board of directors for reasonable travel and out-of-pocket expenses incurred in attending meetings of our board of directors and committees of our board of directors.

	<u>Fees Earned or Paid in Cash (\$)</u>	<u>Option Awards (\$)(1)</u>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</u>
David Johnson	–	320,000	–	320,000
George S. Golumbeski, Ph.D.	50,000(2)	–	–	50,000
Raj Parekh, Ph.D.	–	–	–	–
Joel Jean-Mairet, Ph.D.	–	–	–	–
Giovanni Mariggi, Ph.D.	–	–	–	–
Arthur Pappas	–	–	–	–
Casper Breum	–	–	–	–
Christian Schetter, Ph.D.	–	–	–	–

- (1) Amounts represent the aggregate grant date fair value of the option awards granted to our directors during our fiscal year ended December 31, 2020, computed in accordance with FASB ASC Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in Note 9 to our financial statements for the year ended December 31, 2020, included elsewhere in this prospectus. This amount does not correspond to the actual value that may be recognized by the director upon exercise of the applicable award or sale of the underlying shares of stock. Except as noted below, none of our directors held options to purchase our common stock or any other stock awards as of December 31, 2020.
- (2) Amount was paid pursuant to a board offer letter dated November 13, 2019, pursuant to which Dr. Golumbeski is entitled to receive \$50,000 annually for his board service, to be paid on a quarterly basis, as well as a one-time option grant for 151,897 shares. This compensation arrangement will be replaced by the non-employee director compensation policy we intend to adopt in connection with this offering.

	<u>Aggregate Number of Shares Subject to Stock Options</u>
David Johnson	116,788
George Golumbeski	151,897

### ***Non-Employee Director Equity Grants in Connection with Our Initial Public Offering***

In October 2021, our board of directors approved one-time stock option grants for our non-employee directors that are serving on our board as of the effective time of the registration statement of which this prospectus forms a part, that will be effective immediately upon such time. The stock options will be granted under our 2021 Plan. Each such non-employee director shall receive an option to purchase 16,000 shares of our common stock at the initial public offering price per share, which option will vest on the first anniversary of the grant date, subject to continued service to us through the applicable vesting date. The non-executive chairman shall receive an option to purchase an additional 8,000 shares of our common stock (24,000 total) under the same vesting schedule

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outlined above. At their election, Giovanni Mariggi and Karan Takhar shall not be granted stock options for which they would otherwise be eligible as a non employee director.

### **Non-Employee Director Compensation Policy**

In connection with this offering, we have adopted a non-employee director compensation policy that will become effective upon the completion of this offering and will be designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee will be paid cash compensation from and after the completion of this offering, as set forth below:

<b>Board of Directors:</b>	
Members	\$ 40,000
Additional retainer for non-executive chair	\$ 30,000
<b>Audit Committee:</b>	
Members (other than chair)	\$ 7,500
Retainer for chair	\$ 15,000
<b>Compensation Committee:</b>	
Members (other than chair)	\$ 5,000
Retainer for chair	\$ 10,000
<b>Nominating and Corporate Governance Committee:</b>	
Members (other than chair)	\$ 4,000
Retainer for chair	\$ 8,000

In addition, the non-employee director compensation policy provides that, upon initial election to our board of directors, each non-employee director will be granted an option to purchase 32,000 shares of our common stock, or Initial Grant. The Initial Grant will vest in equal installments on the first, second, and third anniversaries of the grant date, subject to continued service through the applicable vesting date. Furthermore, on the date of each annual meeting of stockholders following the completion of this offering, each non-employee director who continues as a non-employee director following such meeting will be granted an annual option to purchase 16,000 shares of our common stock, or Annual Grant. The Annual Grant will vest in full on the earlier of (i) the first anniversary of the grant date or (ii) our next annual meeting of stockholders, subject to continued service through the applicable vesting date. Such awards are subject to full accelerated vesting upon the sale of the company.

We will reimburse all reasonable out-of-pocket expenses incurred by directors for their attendance at meetings of our board of directors or any committee thereof.

Employee directors will receive no additional compensation for their service as a director.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions or series of transactions since January 1, 2018, to which we were or will be a party, in which:

- the amount involved in the transaction exceeds, or will exceed, the lesser of \$120,000 or one percent of the average of the Company's total assets for the last two completed fiscal years; and
- in which any of our executive officers, directors or holders of five percent or more of any class of our capital stock, including their immediate family members or affiliated entities, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and our directors are described elsewhere in this prospectus under "Executive Compensation," "Director Compensation—Non-Employee Director Compensation" and Director Compensation—Consulting Agreement with Dr. Golumbeski."

### Private Placements of Securities

#### **Series D-1 Convertible Preferred Stock Financing**

In April 2019, with a subsequent closing in December 2019, we sold an aggregate of 57,878,742 shares of Series D-1 Convertible Preferred Stock at a purchase price of \$0.6911 per share for aggregate proceeds of \$40.0 million. The following table summarizes purchases of our Series D-1 preferred stock by related persons:

<b>Participant</b>	<b>Shares of Series D-1 Preferred Stock</b>	<b>Total Purchase Price (\$)</b>
Entities affiliated with Medicxi(1)	23,151,500	16,000,001.66
Entities affiliated with Advent Life Sciences(2)	2,170,452	1,499,999.38
Lundbeckfond Invest A/S(3)	5,877,660	4,062,050.83
Arix Bioscience Holdings Limited(4)	6,489,636	4,484,987.44
Chiesi Ventures, LP(5)	3,600,418	2,488,248.88
Belinda A. Termeer(6)	3,445,182	2,380,965.28
Ysios Biofund II Innvierte, F.C.R.(7)	2,893,936	1,999,999.17
Columbus Innvierte, F.C.R.(8)	3,161,738	2,185,076.98

- (1) Entities affiliated with Medicxi collectively beneficially own more than five percent of our outstanding capital stock. Giovanni Mariggi, Ph.D. is a member of Medicxi and a member of our board of directors.
- (2) Entities affiliated with Advent Life Sciences collectively beneficially own more than five percent of our outstanding capital stock. Raj Parekh, Ph.D. is a member of Advent Life Sciences and a member of our board of directors.
- (3) Lundbeckfond Invest A/S beneficially owns more than five percent of our outstanding capital stock.
- (4) Arix Bioscience Holdings Limited beneficially owns more than five percent of our outstanding capital stock.
- (5) Chiesi Ventures, LP beneficially owns more than five percent of our outstanding capital stock.
- (6) Belinda A. Termeer beneficially owns more than five percent of our outstanding capital stock.
- (7) Ysios Biofund II Innvierte, F.C.R. beneficially owns more than five percent of our outstanding capital stock.
- (8) Columbus Innvierte, F.C.R. beneficially owns more than five percent of our outstanding capital stock.

**Series D-2 Convertible Preferred Stock Financing**

In June 2020, with a subsequent closing in March 2021, we sold an aggregate of 24,598,481 shares of Series D-2 Convertible Preferred Stock at a purchase price of \$0.6911 per share for aggregate proceeds of \$17.0 million. The following table summarizes purchases of our Series D-2 preferred stock by related persons:

<b>Participant</b>	<b>Shares of Series D-2 Preferred Stock</b>	<b>Total Purchase Price (\$)</b>
Entities affiliated with Medicxi(1)	5,240,033	3,621,386.80
Entities affiliated with Advent Life Sciences(2)	2,881,479	1,991,390.14
Lundbeckfond Invest A/S(3)	2,762,391	1,909,088.42
Arix Bioscience Holdings Limited(4)	2,300,993	1,590,216.26
Chiesi Ventures, LP(5)	2,204,268	1,523,369.61
Belinda A. Termeer(6)	2,109,229	1,457,688.16
Ysios Biofund II Innvierte, F.C.R.(7)	1,954,299	1,350,616.04
Columbus Innvierte, F.C.R.(8)	1,935,697	1,337,760.20

- (1) Entities affiliated with Medicxi collectively beneficially own more than five percent of our outstanding capital stock. Giovanni Mariggi, Ph.D. is a member of Medicxi and a member of our board of directors.
- (2) Entities affiliated with Advent Life Sciences collectively beneficially own more than five percent of our outstanding capital stock. Raj Parekh, Ph.D. is a member of Advent Life Sciences and a member of our board of directors.
- (3) Lundbeckfond Invest A/S beneficially owns more than five percent of our outstanding capital stock.
- (4) Arix Bioscience Holdings Limited beneficially owns more than five percent of our outstanding capital stock.
- (5) Chiesi Ventures, LP beneficially owns more than five percent of our outstanding capital stock.
- (6) Belinda A. Termeer beneficially owns more than five percent of our outstanding capital stock.
- (7) Ysios Biofund II Innvierte, F.C.R. beneficially owns more than five percent of our outstanding capital stock.
- (8) Columbus Innvierte, F.C.R. beneficially owns more than five percent of our outstanding capital stock.

**Series E Convertible Preferred Stock Financing**

In March 2021, we sold an aggregate of 102,671,041 shares of Series E Convertible Preferred Stock at a purchase price of \$0.7839 per share for aggregate proceeds of \$80.5 million. The following table summarizes purchases of our Series E preferred stock by related persons:

<b>Participant</b>	<b>Shares of Series E Preferred Stock</b>	<b>Total Purchase Price (\$)</b>
Matrix Capital Management Master Fund, LP(1)	31,891,823	25,000,000.05
Citadel-Multi Strategy Equities Master Fund Ltd.(2)	25,513,458	19,999,999.73
Entities affiliated with Medicxi(3)	3,528,050	2,765,638.40
Entities affiliated with Advent Life Sciences(4)	2,241,492	1,757,105.58
Lundbeckfond Invest A/S(5)	2,148,857	1,684,489.00
Arix Bioscience Holdings Limited(6)	2,284,228	1,790,606.33
Chiesi Ventures, LP(7)	2,188,207	1,715,335.47
Belinda A. Termeer(8)	2,039,933	1,599,103.48
Ysios Biofund II Innvierte, F.C.R.(9)	1,520,244	1,191,719.27
Velocity Capital Management LLC(10)	1,913,509	1,499,999.71
Columbus Innvierte, F.C.R.(11)	1,921,594	1,506,337.54

- (1) Karan Takhar is an affiliate of Matrix Capital Management Master Fund, LP and a member of our board of directors.

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- (2) Citadel-Multi Strategy Equities Master Fund Ltd. beneficially owns more than five percent of our outstanding capital stock.
- (3) Entities affiliated with Medicxi collectively beneficially own more than five percent of our outstanding capital stock. Giovanni Mariggi, Ph.D. is an affiliate of Medicxi and a member of our board of directors.
- (4) Entities affiliated with Advent Life Sciences collectively beneficially own more than five percent of our outstanding capital stock. Raj Parekh, Ph.D. is an affiliate of Advent Life Sciences and a member of our board of directors.
- (5) Lundbeckfond Invest A/S beneficially owns more than five percent of our outstanding capital stock.
- (6) Arix Bioscience Holdings Limited beneficially owns more than five percent of our outstanding capital stock.
- (7) Chiesi Ventures, LP beneficially owns more than five percent of our outstanding capital stock.
- (8) Belinda A. Termeer beneficially owns more than five percent of our outstanding capital stock.
- (9) Ysios Biofund II Innvierte, F.C.R. beneficially owns more than five percent of our outstanding capital stock.
- (10) David Johnson is an affiliate of Velocity Capital Management LLC. David Johnson is a member of our board of directors.
- (11) Columbus Innvierte, F.C.R. beneficially owns more than five percent of our outstanding capital stock.

### **Other Agreements with Our Stockholders**

In connection with our Series E convertible preferred stock financing, we entered into investors' rights, voting and right of first refusal and co-sale agreements containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of our preferred stock and certain holders of our common stock. These stockholder agreements will terminate upon the closing of this offering, except for the registration rights granted under our investors' rights agreement, as more fully described in "Description of Capital Stock—Registration Rights."

### **Indemnification Agreements**

We have entered into agreements to indemnify our directors and executive officers. These agreements will, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on our behalf or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

### **Policies for Approval of Related Party Transactions**

Our board of directors reviews and approves transactions with directors, officers and holders of five percent or more of our voting securities and their affiliates, each a related party. Prior to this offering, the material facts as to the related party's relationship or interest in the transaction are disclosed to our board of directors prior to their consideration of such transaction, and the transaction is not considered approved by our board of directors unless a majority of the directors who are not interested in the transaction approve the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party's relationship or interest in the transaction are disclosed to the stockholders, who must approve the transaction in good faith.

In connection with this offering, we have adopted a written related party transactions policy that such transactions must be approved by our audit committee. This policy will become effective on the date on which the registration statement of which this prospectus is part is declared effective by the SEC.

**PRINCIPAL STOCKHOLDERS**

The following table sets forth certain information known to us regarding beneficial ownership of our capital stock as of September 30, 2021, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each person or group of affiliated persons known by us to be the beneficial owner of more than five percent of our capital stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power with respect to the securities as well as any shares of common stock that the individual or entity has the right to acquire within 60 days of September 30, 2021 through the exercise of stock options or other rights. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Except as noted by footnote, and subject to community property laws where applicable, we believe, based on the information provided to us, that the persons and entities named in the table below have sole voting and investment power with respect to all common stock shown as beneficially owned by them.

Each individual or entity shown on the table has furnished information with respect to beneficial ownership. Unless otherwise indicated, the address for each beneficial owner is c/o Aura Biosciences, Inc., 85 Bolton St., Cambridge, MA 02140.

The percentage of beneficial ownership prior to this offering in the table below is based on 23,009,613 shares of common stock deemed to be outstanding as of September 30, 2021, assuming the conversion of all outstanding shares of our preferred stock immediately prior to the completion of this offering, and the percentage of beneficial ownership at this offering in the table below is based on 28,409,613 shares of common stock to be outstanding after the closing of the offering. The information in the table below assumes no exercise of the underwriters' option to purchase additional shares.

<u>Name of Beneficial Owner</u>	<u>Number of Shares Beneficially Owned</u>	<u>Percentage of Shares Outstanding Beneficially Owned</u>	
		<u>Before Offering</u>	<u>After Offering</u>
Entities affiliated with Medicxi(1)	2,329,892	10.1%	8.2%
Matrix Capital Management Master Fund, LP(2)	2,327,870	10.1%	8.2%
Citadel-Multi Strategy Equities Master Fund Ltd.(3)	1,862,296	8.1%	6.6%
Entities affiliated with Advent Life Sciences(4)	1,843,841	8.0%	6.5%
Lundbeckfond Invest A/S(5)	1,767,652	7.7%	6.2%
Arix Bioscience Holdings Limited(6)	1,508,483	6.6%	5.3%
Chiesi Ventures, LP(7)	1,445,071	6.3%	5.1%
Belinda A. Termeer(8)	1,444,941	6.3%	5.1%
Columbus Innvierte, F.C.R.(9)	1,269,000	5.5%	4.5%
Ysios Biofund II Innvierte, F.C.R.(10)	1,250,550	5.4%	4.4%

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Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Outstanding Beneficially Owned	
		Before Offering	After Offering
<b>Named Executive Officers and Directors:</b>			
Elisabet de los Pinos, Ph.D.(11)	712,760	3.0%	2.5%
Cadmus Rich(12)	148,212	*	*
Julie Feder(13)	113,775	*	*
David Johnson(14)	200,499	*	*
Giovanni Mariggi, Ph.D.	—	—	—
Raj Parekh, Ph.D.	—	—	—
Sapna Srivastava, Ph.D.(15)	6,706	*	*
Karan Takhar	—	—	—
Antony Mattessich(16)	2,235	*	*
All executive officers and directors as a group (11 persons)(17)	1,184,187	5.0%	4.0%

\* Less than one percent.

- (1) Consists of 1,650,676 shares issuable upon the conversion of Series D-1 Convertible Preferred Stock, 373,606 shares issuable upon the conversion of Series D-2 Convertible Preferred Stock and 251,545 shares issuable upon the conversion of Series E Convertible Preferred Stock held by Medicxi Growth I LP, a Jersey limited partnership ("Medicxi Growth I") and 39,214 shares issuable upon the conversion of Series D-1 Convertible Preferred Stock, 8,876 shares issuable upon the conversion of Series D-2 Convertible Preferred Stock and 5,975 shares issuable upon the conversion of Series E Convertible Preferred Stock held by Medicxi Growth Co-Invest I LP, a Jersey limited partnership ("Medicxi Growth Co-Invest I", and together with Medicxi Growth I, the "Medicxi Funds"). Medicxi Growth I GP Limited, a Jersey limited liability company ("MGI GP"), is the sole managing general partner of the Medicxi Funds, and Medicxi Ventures Management (Jersey) Limited, a Jersey limited liability company ("Medicxi Manager"), is the sole manager of the Medicxi Funds. MGI GP and Medicxi Manager may be deemed to have voting and dispositive power over the shares held by the Medicxi Funds. The share ownership reported by the Medicxi Funds does not include any shares beneficially owned by Index Ventures Life VI (Jersey) LP and Yucca (Jersey) SLP, and each of the Medicxi Funds and their affiliates disclaim beneficial ownership of the securities beneficially owned by Index Ventures Life VI (Jersey) LP, Yucca (Jersey) SLP and their affiliates. Giovanni Mariggi, Ph.D. is a member of Medicxi and a member of our board of directors. The address of the principal business office of each of the Medicxi Funds is c/o Intertrust Fund Services (Jersey) Limited, 44 Esplanade, St. Helier, Jersey JE4 9WG.
- (2) Consists of 2,327,870 shares issuable upon the conversion of Series E Convertible Preferred Stock held by Matrix Capital Management Master Fund, LP (the "Matrix Fund"). Matrix Capital Management Company, LP, the investment adviser of the Matrix Fund, has discretionary authority to vote and dispose of the shares held by the Matrix Fund and may be deemed to be the beneficial owner of these shares. David Goel, in his capacity as the sole Managing General Partner of Matrix Capital Management Company, LP, may also be deemed to have voting and dispositive power over the shares held by the Matrix Fund. The mailing address for Matrix is 1000 Winter Street, Suite 4500, Waltham, Massachusetts 02451.
- (3) Consists of 1,862,296 shares issuable upon the conversion of Series E Convertible Preferred Stock held of record by Citadel Multi-Strategy Equities Master Fund Ltd. ("Citadel"). Citadel Advisors LLC ("Citadel Advisors") is the portfolio manager of Citadel. Citadel Advisors Holdings LP ("CAH") is the sole member of Citadel Advisors. Citadel GP LLC ("CGP") is the general partner of CAH. Kenneth Griffin owns a controlling interest in CGP. Mr. Griffin, as the owner of a controlling interest in CGP, may be deemed to have shared power to vote or direct the vote of, and/or shared power to dispose or to direct the disposition of, the shares held by Citadel. The foregoing should



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- not be construed as an admission that Mr. Griffin or any of the Citadel related entities is the beneficial owner of any of our securities other than the securities actually owned by such person (if any). The address for Citadel is 601 Lexington Ave., New York, NY 10022.
- (4) Consists of 495,704 shares issuable upon the conversion of Series B Convertible Preferred Stock, 335,882 shares issuable upon the conversion of Series C-1 Convertible Preferred Stock, 426,822 shares issuable upon the conversion of Series C-2 Convertible Preferred Stock, 152,015 shares issuable upon the conversion of Series D-1 Convertible Preferred Stock, 12,652 shares issuable upon the conversion of Series D-2 Convertible Preferred Stock and 8,934 shares issuable upon the conversion of Series E Convertible Preferred Stock held by Advent Life Sciences Fund I LP, 20,907 shares issuable upon the conversion of Series B Convertible Preferred Stock, 14,165 shares issuable upon the conversion of Series C-1 Convertible Preferred Stock, 18,003 shares issuable upon the conversion of Series C-2 Convertible Preferred Stock, 6,412 shares issuable upon the conversion of Series D-1 Convertible Preferred Stock, 532 shares issuable upon the conversion of Series D-2 Convertible Preferred Stock and 376 shares issuable upon the conversion of Series E Convertible Preferred Stock held by Advent Life Sciences LLP (“ALS”), 142,640 shares issuable upon the conversion of Series D-2 Convertible Preferred Stock and 112,539 shares issuable upon the conversion of Series E Convertible Preferred Stock held by Advent Life Sciences Fund III LP, 6,100 shares issuable upon the conversion of Series D-2 Convertible Preferred Stock and 4,813 shares issuable upon the conversion of Series E Convertible Preferred Stock held by ALS III Carry and Co-Invest LP and 48,397 shares issuable upon the conversion of Series D-2 Convertible Preferred Stock and 36,948 shares issuable upon the conversion of Series E Convertible Preferred Stock held by Advent-Harrington Impact Fund LP. (collectively, the “Advent Funds”). ALS is the manager of the Advent Funds and has voting and dispositive power over the shares held by the Advent Funds. Rajesh Parekh, Ph.D., a member of our board of directors, is a General Partner of ALS, and may be deemed to have voting and dispositive power over the shares held by ALS. The address of each of the entities is 27 Fitzroy Square, London, United Kingdom W1T 6ES.
- (5) Consists of 980,143 shares issuable upon the conversion of Series C-1 Convertible Preferred Stock, 429,026 shares issuable upon the conversion of Series D-1 Convertible Preferred Stock, 201,633 shares issuable upon the conversion of Series D-2 Convertible Preferred Stock and 156,850 shares issuable upon the conversion of Series E Convertible Preferred Stock held by Lundbeckfond Invest A/S, or Lundbeckfond. Lundbeckfond is wholly-owned by the Lundbeck Foundation, and the board of directors of the Lundbeckfond Foundation consists of Jørgen Huno Rasmussen, Steffen Kragh, Lars Holmqvist, Susanne Krüger Kjær, Michael Kjær, Peter Schütze, Gunhild Waldemar, Ludovic Tranholm Otterbein, Vagn Flink Møller Pedersen, Henrik Villsen Andersen and Peter Adler Würtzen. The board of directors of the Lundbeck Foundation serve as the board members of Lundbeckfond. No individual member of the Lundbeckfond board of directors is deemed to hold any beneficial ownership or reportable pecuniary interest in the shares held by Lundbeckfond. The board of directors of Lundbeckfond makes decisions with respect to investments made by Lundbeckfond, and the board of directors of Lundbeckfond and Lene Skole, the chief executive officer of Lunbeckfonden, may be deemed to share voting and investment authority over the shares held by Lundbeckfond. The address of Lundbeckfond Invest A/S is Scherfigsvej 7 DK-2100, Copenhagen Ø, Denmark.
- (6) Consists of 700,101 shares issuable upon the conversion of Series C-1 Convertible Preferred Stock, 473,696 shares issuable upon the conversion of Series D-1 Convertible Preferred Stock, 167,995 shares issuable upon the conversion of Series D-2 Convertible Preferred Stock and 166,731 shares issuable upon the conversion of Series E Convertible Preferred Stock. The securities are held by Arix Bioscience Holdings Limited (“Arix Ltd.”). Arix Bioscience Plc is the sole owner and parent of Arix Ltd. and may be deemed to indirectly beneficially own the shares held by

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- Arix Ltd. The Arix Investment Committee, composed of Mark Chin, Peregrine Moncreiffe, Isaac Kohlberg and Maureen O'Connell, may be deemed to share voting and investment power over the shares held by Arix Ltd. The address of Arix Ltd. is Duke Street House, 50 Duke Street, London, W1K 6JL, United Kingdom.
- (7) Consists of 295,207 shares issuable upon the conversion of Series B Convertible Preferred Stock, 312,256 shares issuable upon the conversion of Series C-1 Convertible Preferred Stock, 254,186 shares issuable upon the conversion of Series C-2 Convertible Preferred Stock, 262,804 shares issuable upon the conversion of Series D-1 Convertible Preferred Stock, 160,895 shares issuable upon the conversion of Series D-2 Convertible Preferred Stock and 159,723 shares issuable upon the conversion of Series E Convertible Preferred Stock. Chiesi Ventures, Inc., or Chiesi, as General Partner of Chiesi Ventures, LP, or Chiesi Ventures, may be deemed to have voting and investment authority over the shares held by Chiesi Ventures, LP., and Mr. Giacomo Chiesi is President of, and may be deemed to have control of, Chiesi. By virtue of their respective relationships with Chiesi Ventures, each of Chiesi and Mr. Chiesi may be deemed to indirectly beneficially own the shares of which Chiesi Ventures is the record owner. The address of Chiesi Ventures, LP is 1 Broadway #14, Cambridge, MA 02142.
  - (8) Consists of 16,423 shares of common stock, 4,999 shares issuable upon the conversion of Series A-1 Convertible Preferred Stock, 44,689 shares issuable upon the conversion of Series A-2 Convertible Preferred Stock, 140,136 shares issuable upon the conversion of Series B Convertible Preferred Stock, 200,788 shares issuable upon the conversion of Series C-1 Convertible Preferred Stock, 483,576 shares issuable upon the conversion of Series C-2 Convertible Preferred Stock, 251,473 shares issuable upon the conversion of Series D-1 Convertible Preferred Stock, 153,957 shares issuable upon the conversion of Series D-2 Convertible Preferred Stock and 148,900 shares issuable upon the conversion of Series E Convertible Preferred Stock.
  - (9) Consists of 18,172 shares issuable upon the conversion of Series B Convertible Preferred Stock, 553,080 shares issuable upon the conversion of Series C-1 Convertible Preferred Stock, 185,413 shares issuable upon the conversion of Series C-2 Convertible Preferred Stock, 230,783 shares issuable upon the conversion of Series D-1 Convertible Preferred Stock, 141,290 shares issuable upon the conversion of Series D-2 Convertible Preferred Stock and 140,262 shares issuable upon the conversion of Series E Convertible Preferred Stock. Columbus Innvierte, F.C.R. is administered and managed by Columbus Venture Partnes SGEIC, S.A.U., whose board of directors makes decisions with respect to investments made by Columbus Innvierte, F.C.R. The board of directors of Columbus Venture Partnes SGEIC, S.A.U., composed of Javier García Cogorro, Damiá Tormo Carulla and Neil Collen, may be deemed to share voting and investment authority over the shares held by Columbus Innvierte, F.C.R. The address of Columbus Innvierte, F.C.R. is Jose Abascal 58, 7D 28003, Madrid, Spain.
  - (10) Consists of 221,404 shares issuable upon the conversion of Series B Convertible Preferred Stock, 373,656 shares issuable upon the conversion of Series C-1 Convertible Preferred Stock, 190,639 shares issuable upon the conversion of Series C-2 Convertible Preferred Stock, 211,236 shares issuable upon the conversion of Series D-1 Convertible Preferred Stock, 142,649 shares issuable upon the conversion of Series D-2 Convertible Preferred Stock and 110,966 shares issuable upon the conversion of Series E Convertible Preferred Stock. Joël Jean-Mairet, Julia Salaverria and Karen Wagner, managing Partners at Ysios Capital Partners SGEIC, SAU, management company of Ysios Biofund II Innvierte FCR, may be deemed to share voting and investment authority over the shares held by Ysios Biofund II Innvierte FCR. The address of Ysios Biofund II Innvierte, F.C.R. is Avenida de la Libertad 25, 4th Floor 20004 San Sebastián, Spain.
  - (11) Consists of (i) 131,412 shares of common stock held of record by EdIP Revocable Trust and (ii) 581,348 shares of common stock that the person has the right to acquire within 60 days of September 30, 2021 through the exercise of stock options.
  - (12) Consists of shares of common stock that the person has the right to acquire within 60 days of September 30, 2021 through the exercise of stock options.

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- (13) Consists of shares of common stock that the person has the right to acquire within 60 days of September 30, 2021 through the exercise of stock options.
- (14) Consists of (i) 139,672 shares issuable upon the conversion of Series E Convertible Preferred Stock held by Velocity Capital Management LLC, an entity that Mr. Johnson is the sole member of, and (ii) 60,827 shares of common stock that the person has the right to acquire within 60 days of September 30, 2021 through the exercise of stock options, which is held individually by Mr. Johnson.
- (15) Consists of shares of common stock that the person has the right to acquire within 60 days of September 30, 2021 through the exercise of stock options.
- (16) Consists of shares of common stock that the person has the right to acquire within 60 days of September 30, 2021 through the exercise of stock options.
- (17) Consists of (i) 271,084 shares of common stock and (ii) 913,103 shares of common stock that the persons have the right to acquire within 60 days of September 30, 2021 through the exercise of stock options.

## DESCRIPTION OF CAPITAL STOCK

*The following descriptions are summaries of the material terms of our tenth amended and restated certificate of incorporation, which will be effective upon the closing of this offering and amended and restated bylaws, which became effective upon the effectiveness of the registration statement of which this prospectus is a part. The descriptions of the common stock and preferred stock give effect to changes to our capital structure that will occur immediately prior to the completion of this offering. We refer in this section to our tenth amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.*

### General

Upon completion of this offering, our authorized capital stock will consist of 150,000,000 shares of common stock, par value \$0.00001 per share, and 10,000,000 shares of preferred stock, par value \$0.00001 per share, all of which shares of preferred stock will be undesignated.

As of June 30, 2021, 439,068 shares of our common stock were outstanding and held by 102 stockholders of record. This amount assumes the conversion of all outstanding shares of our preferred stock into common stock, which will occur immediately prior to the closing of this offering.

### Common stock

The holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

### Preferred stock

Immediately prior to the completion of this offering, all outstanding shares of our preferred stock will be converted into shares of our common stock. Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our Company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

### Registration rights

Upon the completion of this offering, the holders of 22,829,179 shares of our common stock, including those issuable upon the conversion of preferred stock, will be entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of our Investor Rights Agreement between us and the holders of our preferred stock. The Investor

Rights Agreement includes demand registration rights, short-form registration rights, and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

***Demand registration rights***

Beginning six months after the completion of this offering, the holders of 22,829,179 shares of our common stock, including those issuable upon the conversion of shares of our preferred stock upon closing of this offering, will be entitled to demand registration rights. Under the terms of the Investor Rights Agreement, we will be required, upon the written request of a majority of holders of the registrable securities then outstanding that would result in an aggregate offering price of at least \$5.0 million, to file a registration statement and to use commercially reasonable efforts to effect the registration of all or a portion of these shares for public resale.

***Short-form registration rights***

Upon the completion of this offering, the holders of 22,829,179 shares of our common stock, including those issuable upon the conversion of shares of our preferred stock upon closing of this offering, are also entitled to short-form registration rights. Pursuant to the Investor Rights Agreement, if we are eligible to file a registration statement on Form S-3, upon the written request from any such holder to sell registrable securities at an aggregate price of at least \$3.0 million, we will be required to use commercially reasonable efforts to effect a registration of such shares. We are required to effect only two registrations in any twelve-month period pursuant to this provision of the investor rights agreement.

***Piggyback registration rights***

Upon the completion of this offering, the holders of 22,829,179 shares of our common stock, including those issuable upon the conversion of shares of our preferred stock upon closing of this offering, are entitled to piggyback registration rights. If we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions contained in the Investor Rights Agreement, we and the underwriters may limit the number of shares included in the underwritten offering to the number of shares which we and the underwriters determine in our sole discretion will not jeopardize the success of the offering.

***Indemnification***

The Investor Rights Agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

***Expiration of registration rights***

The demand registration rights and short-form registration rights granted under the Investor Rights Agreement will terminate on the fifth anniversary of the completion of this offering.

**Anti-takeover effects of our certificate of incorporation and bylaws and Delaware Law**

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

***Board composition and filling vacancies***

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of

incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

***No written consent of stockholders***

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

***Meetings of stockholders***

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

***Advance notice requirements***

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

***Amendment to certificate of incorporation and bylaws***

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, and limitation of liability must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of a majority of the outstanding shares entitled to vote on the amendment, voting together as a single class, except that the amendment of the provisions relating to notice of stockholder business and nominations and special meetings must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

***Undesignated preferred stock***

Upon the completion of this offering, our certificate of incorporation will provide for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred

stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

#### **Exclusive Forum**

Our amended and restated bylaws to be adopted upon the completion of this offering will provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any state law claims for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers and employees to us or our stockholders; (3) any action asserting a claim arising pursuant to the Delaware General Corporation Law or our certificate of incorporation or by-laws (including the interpretation, validity or enforceability thereof); or (4) any action asserting a claim that is governed by the internal affairs doctrine; provided, however, that this provision shall not apply to any causes of action arising under the Securities Act or the Exchange Act. In addition, our amended and restated bylaws will provide that, unless we consent to an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action under the Securities Act (the Federal Forum Provision). Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to these forum provisions. These forum provisions may impose additional costs on stockholders and may limit our stockholders' ability to bring a claim in a forum they find favorable, and the designated courts may reach different judgments or results than other courts. In addition, there is uncertainty as to whether our Federal Forum Provision will be enforced, which may impose additional costs on us and our stockholders.

#### **Section 203 of the Delaware General Corporation Law**

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or

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- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges, or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

### **Nasdaq Global Market listing**

Our common stock has been approved for listing on The Nasdaq Global Market under the trading symbol "AURA."

### **Transfer agent and registrar**

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, Massachusetts 02021, and its telephone number is (800) 962-4284.



## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our shares. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares outstanding as of June 30, 2021, upon the completion of this offering, 28,409,613 shares of our common stock will be outstanding, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below. No shares of our common stock are restricted shares of common stock subject to time-based vesting terms.

### Rule 144

In general, a person who has beneficially owned restricted stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares then outstanding, which will equal approximately 284,096 shares immediately after this offering assuming no exercise of the underwriters' option to purchase additional shares, based on the number of shares outstanding as of June 30, 2021; or
- the average weekly trading volume of our common stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

### Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers, or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the effectiveness of the registration statement of which this prospectus forms a part before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under "Underwriting" included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

### Lock-Up Agreements

We, all of our directors and executive officers, and the holders of substantially all of our capital stock and securities convertible into or exchangeable for our capital stock have entered into lock-up

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agreements with the underwriters and/or are subject to market standoff agreements or other agreements with us, which prevents them from selling any of our common stock or any securities convertible into or exercisable or exchangeable for common stock for a period of not less than 180 days from the date of this prospectus without the prior written consent of the representatives, subject to certain exceptions. See the section entitled "Underwriting" appearing elsewhere in this prospectus for more information.

### **Rule 10b5-1 Trading Plans**

Following the completion of this offering, certain of our officers, directors and significant stockholders may adopt written plans, known as Rule 10b5-1 trading plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis to diversify their assets and investments. Under these 10b5-1 trading plans, a broker may execute trades pursuant to parameters established by the officer, director or stockholder when entering into the plan, without further direction from such officer, director or stockholder. Such sales would not commence until the expiration of the applicable lock-up agreements entered into by such officer, director or stockholder in connection with this offering.

### **Registration rights**

Upon completion of this offering, certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration statement. See the section entitled "Description of Capital Stock—Registration rights" appearing elsewhere in this prospectus for more information.

### **Equity incentive plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our shares issued or reserved for issuance under our equity incentive plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above.

**MATERIAL U.S. FEDERAL INCOME TAX  
CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK**

The following discussion is a summary of material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is, for U.S. federal income tax purposes:

- a non-resident alien individual;
- a corporation or any other organization taxable as a corporation for U.S. federal income tax purposes that is created or organized in or under laws other than the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is not subject to U.S. federal income tax on a net income basis; or
- a trust that (1) (a) has not made an election to be treated as a U.S. person under applicable U.S. Treasury regulations and (b) either (i) is not subject to the primary supervision of a court within the United States or (ii) is not subject to the substantial control of one or more U.S. persons or (2) the income of which is not subject to U.S. federal income tax on a net income basis.

This discussion does not address the tax treatment of partnerships or other entities or arrangements that are treated as pass-through entities for U.S. federal income tax purposes or persons that hold their shares of our common stock through partnerships or such other pass-through entities. The tax treatment of a partner in a partnership or other entity or arrangement that is treated as a pass-through entity for U.S. federal income tax purposes generally will depend upon the status of the partner and the activities of the partnership. A partner in a partnership or an investor in any other pass-through entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the Internal Revenue Code, or the Code, existing and proposed U.S. Treasury regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. We have not sought and will not seek any rulings from the Internal Revenue Service, or the IRS, regarding the matters discussed below and there can be no assurance that the IRS will not challenge one or more of the tax consequences described herein or that any such challenge would not be sustained by a court. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a "capital asset" within the meaning of Section 1221 of the Code, which is generally property held for investment.

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, including the alternative minimum tax, the Medicare tax on net investment income, the special tax accounting rules under Section 451(b) of the Code, the rules relating to "qualified small business stock," any U.S. federal tax other than the income tax (including, for example, the estate or gift tax), or any aspects of U.S. state, local or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

1. insurance companies;
2. tax-exempt or governmental organizations;

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3. financial institutions;
4. brokers or dealers in securities;
5. regulated investment companies;
6. pension plans;
7. “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
8. “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code or entities wholly owned by a “qualified foreign pension fund”;
9. persons that own, or are deemed to own, more than 5% of our capital stock;
10. persons deemed to sell our common stock under the constructive sale provisions of the Code;
11. persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
12. persons that hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation; and
13. U.S. expatriates and former citizens or long-term residents of the United States.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local, estate and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

### **Distributions on our common stock**

As described in the “Dividend Policy” section above, we do not intend to pay any dividends in cash or property on our common stock to our stockholders in the foreseeable future. Distributions of cash or property, if any, on shares of our common stock generally 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. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a return of the non-U.S. holder’s investment, up to such holder’s adjusted tax basis in the shares of common stock (not below zero). Any remaining excess will be treated as capital gain, subject to the tax treatment described below in “Gain on sale, exchange or other taxable disposition of shares of our common stock.” Any such distributions will also be subject to the discussion below under the section titled “Withholding and information reporting requirements—FATCA.”

Subject to the discussion in the following two paragraphs in this section, dividends paid to a non-U.S. holder 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 between the United States and such holder’s country of residence. A non-U.S. holder of shares of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder’s country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or a successor form) to the applicable withholding agent and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may generally obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the

United States, are generally exempt from the 30% withholding tax if the non-U.S. holder delivers a properly executed IRS Form W-8ECI, stating that the dividends are so connected and satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional “branch profits tax” at a 30% rate or such lower rate as specified by an applicable income tax treaty between the United States and such holder’s country of residence.

#### **Gain on sale, exchange or other taxable disposition of shares of our common stock**

Subject to the discussion below under “Withholding and information reporting requirements—FATCA,” a non-U.S. holder generally will not be subject to any U.S. federal income tax on any gain realized upon such holder’s sale, exchange or other taxable disposition of shares of our common stock unless:

1. the gain is effectively connected with the non-U.S. holder’s conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the same U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence) may also apply as described above in “Distributions on our common stock” also may apply;
2. the non-U.S. holder is a nonresident alien individual who is present in the United States for a period or periods aggregating 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence) on the gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (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, if any; or
3. we are, or have been, at any time during the five-year period preceding such sale or other taxable disposition (or the non-U.S. holder’s holding period, if shorter) a “U.S. real property holding corporation,” unless our common stock is regularly traded on an established securities market, within the meaning of the relevant provisions of the Code, and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation and the foregoing exception does not apply, then the non-U.S. holder generally will be taxed on its gain derived from the disposition at the U.S. federal income tax rates applicable to United States persons (as defined in the Code). Generally, a corporation is a “U.S. real property holding corporation” only if the fair market value of its “U.S. real property interests” (as defined in the Code and applicable U.S. Treasury regulations) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a “U.S. real property holding corporation” for U.S. federal income tax purposes, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

### **Backup withholding and information reporting**

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on shares of our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on shares of our common stock. Generally, a non-U.S. holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN, W-8BEN-E or W-8ECI (or other applicable IRS Form W-8), or otherwise meets documentary evidence requirements for establishing that it is a non-U.S. holder, or otherwise establishes an exemption. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in “Distributions on our common stock,” generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of shares of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or non-U.S., unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

### **Withholding and information reporting requirements—FATCA**

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax at a rate of 30% on payments of dividends on our common stock paid to a foreign entity unless (i) if the foreign entity is a “foreign financial institution,” such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a “foreign financial institution,” such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Such withholding may also apply to payments of gross proceeds of sales or other dispositions of shares of our common stock, although under proposed U.S. Treasury regulations (the preamble to which specifies that taxpayers, including withholding agents, are generally permitted to rely on them pending finalization), no withholding will apply to payments of gross proceeds. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our shares of common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

**The preceding discussion of material U.S. federal tax considerations is for prospective investors' information only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local, and non-U.S. tax consequences of purchasing, holding, and disposing of our common stock, including the consequences of any proposed changes in applicable laws, as well as tax consequences arising under any state, local, non-U.S. or U.S. federal non-income tax laws such as estate and gift tax or under any applicable tax treaty.**

## UNDERWRITING

We and Cowen and Company, LLC, SVB Leerink LLC and Evercore Group L.L.C., as the representatives of the several underwriters for the offering named below, have entered into an underwriting agreement with respect to the common stock being offered. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally, and not jointly, agreed to purchase from us the number of shares of our common stock set forth opposite its name below.

Underwriter	Number of Shares
Cowen and Company, LLC	1,782,000
SVB Leerink LLC	1,782,000
Evercore Group L.L.C.	1,458,000
BTIG, LLC	378,000
Total	5,400,000

The underwriting agreement provides that the obligations of the underwriters are subject to certain conditions precedent and that the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased, other than those shares covered by the option to purchase additional shares described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

**Option to Purchase Additional Shares.** We have granted to the underwriters an option to purchase up to 810,000 additional shares of our common stock at the public offering price, less the underwriting discounts and commissions. This option is exercisable for a period of 30 days. To the extent that the underwriters exercise this option, the underwriters will purchase additional shares from us in approximately the same proportion as shown in the table above.

**Discounts and Commissions.** The following table shows the public offering price, underwriting discounts and commissions and proceeds, before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Per Share	Total	
		Without Option to Purchase Additional Shares	With Full Option to Purchase Additional Shares
Public offering price	\$ 14.00	\$ 75,600,000	\$ 86,940,000
Underwriting discounts and commissions	\$ 0.98	\$ 5,292,000	\$ 6,085,800
Proceeds, before expenses, to us	\$ 13.02	\$ 70,308,000	\$ 80,854,200

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We estimate that the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$3.0 million and are payable by us. We also have agreed to reimburse the underwriters for their FINRA counsel fee. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering.

The underwriters propose to offer the shares of our common stock to the public at the public offering price set forth on the cover page of this prospectus. The underwriters may offer the shares of our common stock to securities dealers at the public offering price less a concession not in excess of \$0.588 per share. If all of the shares are not sold at the public offering price, the underwriters may change the offering price and other selling terms.

**Discretionary Accounts.** The underwriters do not intend to confirm sales of the shares to any accounts over which they have discretionary authority.

**Market Information.** Prior to this offering, there has been no public market for shares of our common stock. The initial public offering price was determined by negotiations between us and the representatives of the underwriters. In addition to prevailing market conditions, the factors considered in these negotiations included:

- the history of, and prospects for, our company and the industry in which we compete;
- our past and present financial information;
- an assessment of our management; its past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol "AURA".

**Stabilization.** In connection with this offering, the underwriters may engage in stabilizing transactions, overallotment transactions, syndicate covering transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase shares of our common stock so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress.
- Overallotment transactions involve sales by the underwriters of shares of our common stock in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase pursuant to the option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares that the underwriters have the option to purchase. The underwriters may close out any short position by exercising their option to purchase additional shares and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining



the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the option to purchase additional shares. If the underwriters sell more shares than could be covered by exercise of the option to purchase additional shares and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

- Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by that syndicate member is purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on Nasdaq, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

**Passive Market Making.** In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on Nasdaq in accordance with Rule 103 of Regulation M under the Exchange Act, as amended, during a period before the commencement of offers or sales of common stock and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, such bid must then be lowered when specified purchase limits are exceeded.

**Lock-Up Agreements.** Pursuant to certain "lock-up" agreements, we and our executive officers, directors and substantially all of our other securityholders, have agreed, subject to certain exceptions, not to, and not to cause or direct any affiliates to, offer, sell, lend, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement (including, without limitation, 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) that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of, directly or indirectly, or make any demand or request or exercise any right with respect to the registration of, or file with the SEC a registration statement under the Securities Act relating to, any common stock or securities convertible into or exchangeable or exercisable for any common stock without the prior written consent of Cowen and Company, LLC, SVB Leerink LLC and Evercore Group L.L.C. for a period of 180 days after the date of the pricing of the offering.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. The exceptions permit us, among other things and subject to restrictions, to: (i) issue common stock or options pursuant to employee benefit plans, (ii) issue common stock upon exercise of outstanding options or warrants, (iii) issue securities in connection with acquisitions or similar transactions or (iv) file registration statements on Form S-8. The exceptions permit parties to the "lock-up" agreements, among other things and subject to restrictions, to: (i) convert outstanding

convertible preferred stock into shares of common stock in connection with this offering, (ii) if a natural person, transfer as a bona fide gift, by will or intestate succession, (iii) if a business entity, transfer to an equityholder, if not for value, (iv) if a business entity, in connection with a sale or bona fide transfer in a single transaction of all or substantially all equity interests or to an affiliate, (v) transfer pursuant to change in control, (vi) if a trust, distribute to beneficiaries of a trust, (vii) transfer pursuant to agreements in effect as of the date of execution where we have an option to repurchase shares upon termination of the signatory, (viii) enter into transactions related to common stock sold in this offering or common stock acquired in open market transactions following this offering, (ix) enter into a 10b5-1(c) trading plan, provided the plan does not permit sales during the lock-up period, (x) transfer to satisfy tax withholding obligations pursuant to arrangements disclosed herein and (xi) transfer pursuant to a court order or order of regulatory agency. In addition, the lock-up provision will not restrict broker-dealers from engaging in market making and similar activities conducted in the ordinary course of their business.

Cowen and Company, LLC, SVB Leerink LLC, and Evercore Group L.L.C., in their sole discretion, may release our common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release our common stock and other securities from lock-up agreements, Cowen and Company, LLC, SVB Leerink LLC, and Evercore Group L.L.C. will consider, among other factors, the holder's reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time of the request. In the event of such a release or waiver for one of our directors or officers, Cowen and Company, LLC, SVB Leerink LLC and Evercore Group L.L.C. shall provide us with notice of the impending release or waiver at least three business days before the effective date of such release or waiver and we will announce the impending release or waiver by issuing a press release at least two business days before the effective date of the release or waiver.

**Electronic Offer, Sale and Distribution of Shares.** A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. Cowen and Company, LLC, SVB Leerink LLC and Evercore Group L.L.C. 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 underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

**Other Relationships.** Certain of the underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees.

#### **Selling Restrictions**

**Canada.** The common stock 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 common stock 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

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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.

**United Kingdom.** No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

- (A) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;
- (B) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- (C) in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom 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 "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

**Switzerland.** The securities will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to article 652a or 1156 of the Swiss Federal Code of Obligations.

**European Economic Area.** In relation to each member state of the European Economic Area, each a member state, no shares have been offered or will be offered pursuant to the offering to the public in that member state prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that member state or, where appropriate, approved in another member state and notified to the competent authority in that member state, all in accordance with the Prospectus Regulation, except that shares may be made to the public in that member state at any time:

- (A) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;
- (B) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of 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 of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation. For the purposes of this provision, the expression an "offer to

the public” in relation to shares in any member 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.

**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), or 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.

**Singapore.** Each underwriter has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each underwriter 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, or 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 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 (however 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;

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- (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.

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 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).

**Israel.** In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares under the Israeli Securities Law, 5728 - 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728 - 1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions, or the Addressed Investors; or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728 - 1968, subject to certain conditions, collectively, the Qualified Investors. The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. We have not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728 - 1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our shares to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in the First Addendum to the Israeli Securities Law, 5728 - 1968. In particular, we may request, as a condition to be offered shares, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728 - 1968 and the regulations promulgated thereunder in connection with the offer to be issued shares; (iv) that the shares that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 - 1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 - 1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor’s name, address and passport number or Israeli identification number.

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on our behalf, other than offers made by the underwriters and their respective affiliates, with a view to the final placement of the securities as contemplated in this document. Accordingly, no purchaser of the shares, other than the underwriters, is authorized to make any further offer of shares on our behalf or on behalf of the underwriters.

## LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. The underwriters are being represented by Cooley LLP, Boston, Massachusetts.

## EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2019 and December 31, 2020, and for each of the two years in the period ended December 31, 2020, as set forth in their report. We have 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 MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-260156) under the Securities Act with respect to the common stock we are offering by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the completion of this offering, we will be subject to the informational requirements of the Exchange Act and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at [www.sec.gov](http://www.sec.gov). We also maintain a website at [www.aurabiosciences.com](http://www.aurabiosciences.com). Upon completion of this offering, you may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendment to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

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## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Aura Biosciences, Inc.

### Opinion on the Financial Statements

We have audited the accompanying balance sheets of Aura Biosciences, Inc. (the Company) as of December 31, 2020 and 2019, 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, 2020 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.  
Boston, Massachusetts  
August 9, 2021, except for Note 16(E) as to which the date is October 25, 2021



**Aura Biosciences, Inc.**

**Balance Sheets**  
(in thousands, except share and per share amounts)

	<b>December 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Assets</b>		
Current assets:		
Cash	\$ 17,393	\$ 32,449
Restricted cash and deposits	19	19
Prepaid expenses and other current assets	1,043	878
Total current assets	18,455	33,346
Restricted cash and deposits, net of current portion	75	75
Property and equipment, net	3,574	3,634
<b>Total Assets</b>	<b>\$ 22,104</b>	<b>\$ 37,055</b>
<b>Liabilities, Convertible Preferred Stock, and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	611	2,332
Equipment promissory note	15	-
Accrued expenses and other current liabilities	2,035	3,816
Total current liabilities	2,661	6,148
Deferred rent	8	20
Equipment promissory note	-	49
Warrant liability	72	75
<b>Total Liabilities</b>	<b>2,741</b>	<b>6,292</b>
<b>Commitments and Contingencies (Note 12)</b>		
Series A convertible preferred stock, \$0.00001 par value, 1,701,141 shares authorized, issued and outstanding at December 31, 2020 and 2019, respectively, and a liquidation preference of \$3,403 at December 31, 2020 and December 31, 2019, respectively	3,368	3,368
Series A-1 convertible preferred stock, \$0.00001 par value, 3,298,732 shares authorized, issued, and outstanding at December 31, 2020 and 2019, respectively, and a liquidation preference of \$8,196 at December 31, 2020 and December 31, 2019, respectively	7,837	7,837
Series A-2 convertible preferred stock, \$0.00001 par value, 4,325,021 shares authorized, and 4,324,998 shares issued and outstanding at December 31, 2020 and 2019, respectively, and a liquidation preference of 5,373 at December 31, 2020 and December 31, 2019, respectively	5,373	5,373
Series B convertible preferred stock, \$0.00001 par value, 22,705,646 shares authorized, and 22,531,819 shares issued and outstanding at December 31, 2020 and 2019, respectively, and a liquidation preference of \$37,429 and \$35,464 at December 31, 2020 and December 31, 2019, respectively	20,806	20,806
Series C-1 convertible preferred stock, \$0.00001 par value, 58,109,711 shares authorized, issued and outstanding at December 31, 2020 and 2019, respectively, and a liquidation preference of \$36,150 and \$34,023 at December 31, 2020 and December 31, 2019, respectively	29,353	29,353
Series C-2 convertible preferred stock, \$0.00001 par value, 33,218,192 shares authorized, issued and outstanding at December 31, 2020 and 2019, respectively, and a liquidation preference of \$14,697 and \$13,847 at December 31, 2020 and December 31, 2019, respectively	11,746	11,746
Series D-1 convertible preferred stock, \$0.00001 par value, 57,878,742 shares authorized, issued and outstanding at December 31, 2020 and 2019, respectively, and a liquidation preference of \$43,908 and \$41,101 at December 31, 2020 and December 31, 2019, respectively	39,686	39,686
Series D-2 convertible preferred stock, \$0.00001 par value, 24,598,481 shares authorized, and 14,469,710 issued and outstanding at December 31, 2020, and a liquidation preference of \$10,176 at December 31, 2020; no shares authorized, issued or outstanding at December 31, 2019	9,907	-
<b>Stockholders' Deficit:</b>		
Common stock, \$0.00001 par value, 232,697,999 and 208,099,518 shares authorized at December 31, 2020 and 2019, respectively, 381,123 and 340,591 shares issued and outstanding at December 31, 2020 and 2019, respectively	-	-
Additional paid-in capital	8,173	7,274
Accumulated deficit	(116,886)	(94,680)
<b>Total Stockholders' Deficit</b>	<b>(108,713)</b>	<b>(87,406)</b>
<b>Total Liabilities, Convertible Preferred Stock, and Stockholders' Deficit</b>	<b>\$ 22,104</b>	<b>\$ 37,055</b>

*The accompanying notes are an integral part of these financial statements.*

## Aura Biosciences, Inc.

Statements of Operations and Comprehensive Loss  
(in thousands except for share and per share data)

	Year Ended December 31,	
	2020	2019
<b>Operating Expenses:</b>		
Research and development	18,042	19,617
General and administrative	4,164	4,523
Total operating expenses	<u>22,206</u>	<u>24,140</u>
Total operating loss	<u>22,206</u>	<u>24,140</u>
Other income (expense):		
Change in fair value of warrant liability	3	(44)
Interest expense, including amortization of discount	(3)	(5)
(Loss) gain from disposal of assets	<u>—</u>	<u>(11)</u>
Total other income (expense)	<u>—</u>	<u>(60)</u>
Net loss and comprehensive loss	<u>\$ (22,206)</u>	<u>\$ (24,200)</u>
Net loss attributable to common stockholders—basic and diluted (Note 13)	<u>\$ (30,132)</u>	<u>\$ (30,229)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (82.06)</u>	<u>\$ (89.36)</u>
Weighted average common stock outstanding—basic and diluted	<u>367,204</u>	<u>338,289</u>

*The accompanying notes are an integral part of these financial statements.*

Aura Biosciences, Inc.

Statements of Convertible Preferred Stock and Stockholders' Deficit  
(in thousands, except share data)

	Convertible Preferred Stock												Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Series A		Series A-1		Series A-2		Series B		Series C-1 and C-2		Series D-1 and D-2		Shares	Amount			
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
<b>Balance, December 31, 2018</b>	<u>1,701,141</u>	<u>\$ 3,368</u>	<u>3,298,732</u>	<u>\$ 7,837</u>	<u>4,324,998</u>	<u>\$ 5,373</u>	<u>22,531,819</u>	<u>\$20,806</u>	<u>91,327,903</u>	<u>\$41,099</u>	<u>-</u>	<u>-</u>	<u>329,511</u>	<u>-</u>	<u>\$ 6,710</u>	<u>\$ (70,480)</u>	<u>\$ (63,770)</u>
Issuance of Series D convertible preferred stock, net of issuance costs of \$314	-	-	-	-	-	-	-	-	-	-	57,878,742	39,686	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	-	-	-	-	-	-	-	-	-	-	507	-	507
Stock option exercises	-	-	-	-	-	-	-	-	-	-	-	-	11,080	-	57	-	57
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	(24,200)	(24,200)
<b>Balance, December 31, 2019</b>	<u>1,701,141</u>	<u>\$ 3,368</u>	<u>3,298,732</u>	<u>\$ 7,837</u>	<u>4,324,998</u>	<u>\$ 5,373</u>	<u>22,531,819</u>	<u>\$20,806</u>	<u>91,327,903</u>	<u>\$41,099</u>	<u>57,878,742</u>	<u>\$39,686</u>	<u>340,591</u>	<u>-</u>	<u>\$ 7,274</u>	<u>\$ (94,680)</u>	<u>\$ (87,406)</u>
Issuance of Series D convertible preferred stock, net of issuance costs of \$93	-	-	-	-	-	-	-	-	-	-	14,469,710	9,907	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	-	-	-	-	-	-	-	-	-	-	736	-	736
Stock option exercises	-	-	-	-	-	-	-	-	-	-	-	-	40,532	-	163	-	163
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	(22,206)	(22,206)
<b>Balance, December 31, 2020</b>	<u>1,701,141</u>	<u>\$ 3,368</u>	<u>3,298,732</u>	<u>\$ 7,837</u>	<u>4,324,998</u>	<u>\$ 5,373</u>	<u>22,531,819</u>	<u>\$20,806</u>	<u>91,327,903</u>	<u>\$41,099</u>	<u>72,348,452</u>	<u>\$49,593</u>	<u>381,123</u>	<u>-</u>	<u>\$ 8,173</u>	<u>\$ (116,886)</u>	<u>\$ (108,713)</u>

The accompanying notes are an integral part of these financial statements.

## Aura Biosciences, Inc.

Statements of Cash Flows  
(in thousands)

	Year ended December 31,	
	2020	2019
<b>Cash flows from operating activities:</b>		
Net loss	\$ (22,206)	\$ (24,200)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	831	509
Change in fair value of warrant liability	(3)	43
Stock-based compensation expense	736	507
Gain on disposal of property and equipment	–	11
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(165)	(139)
Accounts payable	(1,721)	1,043
Accrued expenses and other liabilities	(1,793)	1,560
<b>Net cash used in operating activities</b>	<u>(24,321)</u>	<u>(20,666)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(771)	(2,221)
<b>Net cash used in investing activities</b>	<u>(771)</u>	<u>(2,221)</u>
Cash flows from financing activities:		
Proceeds from exercise of stock options	163	57
Payment of issuance costs for Series C-1 convertible preferred stock	–	(13)
Proceeds from issuance of Series D convertible preferred stock, net of issuance costs	9,907	39,719
Payments made on equipment promissory note	(34)	(37)
<b>Net cash provided by financing activities</b>	<u>10,036</u>	<u>39,726</u>
<b>Net (decrease) increase in cash, cash equivalents and restricted cash</b>	<u>(15,056)</u>	<u>16,839</u>
<b>Cash, cash equivalents and restricted cash at beginning of period</b>	<u>32,543</u>	<u>15,704</u>
<b>Cash, cash equivalents and restricted cash at end of period</b>	<u>\$ 17,487</u>	<u>\$ 32,543</u>
<b>Supplemental Disclosure of Cash Flow Information:</b>		
Interest expense related to equipment promissory note	\$ (3)	\$ (5)
Series C-1 issuance costs unpaid at year end	\$ –	\$ 10
Series D issuance costs unpaid at year end	\$ –	\$ 23

The accompanying notes are an integral part of these financial statements.

**Aura Biosciences, Inc.**

**Notes to Financial Statements  
Years Ended December 31, 2020 and 2019**

**1. Description of Business**

Aura Biosciences, Inc. (the “Company” or “Aura”) is a clinical-stage biotechnology company leveraging its novel targeted oncology platform to develop a potential new standard of care across multiple cancer indications, with an initial focus on ocular and urologic oncology. The Company’s proprietary platform enables the targeting of a broad range of solid tumors using Virus-Like Particles, or VLPs, that can be conjugated with drugs or loaded with nucleic acids to create Virus-Like Drug Conjugates, or VDCs. The Company’s VDCs are largely agnostic to tumor type and can recognize a surface marker, known as HSPGs, that are specifically modified and more broadly expressed on many tumors. The Company is developing AU-011, its first VDC product candidate for the first line treatment of primary choroidal melanoma, a rare disease with no drugs approved. The Company is also developing AU-011 for additional ocular oncology indications and in non-muscle invasive bladder cancer. Aura’s team combines expertise in cancer cell biology, ophthalmology, and targeted therapies together with experience in the development and commercialization of orphan products for significant unmet medical needs. Aura’s headquarters are located in Cambridge, Massachusetts.

The Company’s operations to date have consisted primarily of conducting research and development and raising capital.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, the successful development and commercialization of products, fluctuations in operating results and financial risks, need for additional financing or alternative means of financial support or both to fund its current operating plan, protection of proprietary technology and patent risks, compliance with government regulations, dependence on key personnel and collaborative partners, competition, customer demand, management of growth, and the effectiveness of marketing by the Company.

***Liquidity and Going Concern***

Through December 31, 2020, the Company has funded its operations primarily with proceeds from the initial closing and additional closings of its convertible preferred stock financings and through its license agreements. The Company has incurred recurring losses and negative operating cash flows from operations since its inception, including net losses of \$22.2 million and \$24.2 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, the Company had cash of \$17.4 million and an accumulated deficit of \$116.9 million. The Company expects to continue to generate operating losses for the foreseeable future.

As of the issuance date of these financial statements for the year ended December 31, 2020, the Company has raised an additional \$87.5 million through convertible preferred stock financings in 2021 and expects that its cash will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance of the financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

***Impact of COVID-19***

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced. Since then, COVID-19 coronavirus has spread globally. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic and the U.S. government-imposed travel restrictions on travel between the United States, Europe and certain other countries.

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The outbreak and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as certain worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended. The future progression of the pandemic and its effects on the Company's business and operations are uncertain.

The Company is monitoring the potential impact of COVID-19 on its business and financial statements. The effects of the public health directives and the Company's work-from-home policies may negatively impact productivity, disrupt its business, and delay clinical programs and timelines and future clinical trials, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on its ability to conduct business in the ordinary course. These and similar, and perhaps more severe, disruptions in the Company's operations could negatively impact business, results of operations and financial condition, including its ability to obtain financing.

To date, the Company has not incurred impairment losses in the carrying values of its assets as a result of the pandemic and are not aware of any specific related event or circumstance that would require the Company to revise its estimates reflected in the financial statements.

The Company cannot be certain what the overall impact of the COVID-19 pandemic will be on its business and prospects. The extent to which the COVID-19 pandemic will directly or indirectly impact its business, results of operations, financial condition, and liquidity, including planned and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related effects.

## **2. Summary of Significant Accounting Policies**

### ***Basis of Presentation***

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP").

### ***Use of Estimates***

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant items subject to such estimates and assumptions include the useful lives of property and equipment, deferred tax assets and liabilities and related valuation allowance, fair value of common stock and stock-based compensation, warrant liability and accrued research and development costs. Management bases its estimates on historical experience and on various other market-specific relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

### ***Segment Information***

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment operating exclusively in the United States.

### ***Cash and Restricted Cash***

Cash consists of standard checking accounts. As of December 31, 2020, and 2019, the restricted cash account is comprised of a \$0.1 million security deposit held by the lessor for the Company's facility lease, and a \$0.02 million deposit that is collateral for the Company's corporate credit card.

**Fair Value Measurements**

Accounting Standards Codification 820, Fair Value Measurement (“ASC 820”), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company’s own assumptions (unobservable inputs).

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company’s assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes between the following:

- Level 1—Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2—Inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
- Level 3—Inputs are unobservable inputs that reflect the Company’s own assumptions about the assumptions market participants would use in pricing the asset or liability. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

**Concentration of Credit Risk**

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash. The Company maintains its cash in bank deposit accounts which, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash.

**Property and Equipment**

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful life of the assets. Upon sale or retirement, the cost and accumulated depreciation is eliminated from their respective accounts and the resulting gain or loss is included in income or loss for the period. Repair and maintenance expenditures are charged to expense as incurred. The estimated useful lives of the Company’s respective assets are as follows:

	<u>Estimated Useful Life</u>
Computer equipment	3 years
Laboratory equipment	5 years
Equipment capital lease	5 years
Office furniture	7 years

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated in accordance with the above guidelines once placed into service. Upon retirement or

disposal of property and equipment, the cost and related accumulated depreciation are removed from the balance sheet and any gain or loss is reflected in the statements of operations and comprehensive loss.

***Impairment of Long-Lived Assets***

The Company reviews all long-lived assets for impairment whenever events or circumstances indicate the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by comparison of the carrying value of the assets to the future undiscounted net cash flows expected to be generated by the asset. If such asset is considered to be unrecoverable, the impairment recognized is measured by the difference between the estimated fair value of the asset and its carrying value. The Company did not recognize any material impairments during the years ended December 31, 2020 or 2019.

***Research and Development***

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, facilities costs, depreciation, third-party license fees, and external costs of outside vendors engaged to conduct preclinical development activities and clinical trials as well as to manufacture research and development materials. The Company accrues costs for clinical trial activities and contract manufacturers based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations, clinical study sites, contract manufacturers, laboratories, consultants, or other vendors that perform the activities.

Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred. Such amounts are expensed 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 recognized as research and development expense as incurred if the technology licensed has not reached technological feasibility and has no alternative future uses.

***Patent and Trademark Costs***

All patents and trademark related costs incurred in connection with filing and prosecuting patent and trademark applications are expensed as incurred due to uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the statements of operations and comprehensive loss.

***Leases***

Leases are classified at their inception as either operating or capital leases. The Company recognizes rent expense for its facility lease, which is classified as an operating lease, on a straight-line basis over the respective lease term, inclusive of rent escalation provisions and rent holidays. The difference between rent payments made and straight-line rent expense is recorded as deferred rent.

***Income Taxes***

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's financial statements and/or tax returns. Deferred tax assets and liabilities are based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all the deferred tax asset will not be realized.

The Company provides reserves related to uncertain tax positions when management determines the related tax benefit is not more likely than not to be realized. The determination as to whether the



tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as the consideration of the available facts and circumstances. The Company has no reserves related to uncertain tax positions as of December 31, 2020 and 2019.

Interest and penalty charges, if any, related to uncertain tax positions would be classified as income tax expense in the accompanying statements of operations and comprehensive loss. As of December 31, 2020, and 2019, the Company had no accrued interest related to uncertain tax positions.

***Deferred Offering Costs***

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process preferred stock or common stock 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 convertible preferred stock or in stockholders' deficit as a reduction of additional paid-in capital generated as a result of the offering. Should a planned 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.

***Convertible Preferred Stock Classification***

The Company records all convertible preferred stock upon issuance at its respective fair value or original issuance price less issuance costs. The Company classifies its convertible preferred stock outside of stockholders' deficit as the redemption of such shares is outside the Company's control. The Company does not adjust the carrying values of the convertible preferred stock to redemption value unless and until it becomes probable that the instrument will become redeemable. As of December 31, 2020, and 2019, the Company's convertible preferred stock was not adjusted to redemption value.

***Stock-Based Compensation***

The Company recognizes stock-based compensation expense for all stock-based awards based on their grant date fair value.

The Company recognizes compensation expense over the requisite service period, which is generally the vesting period of the award. For awards that include performance-based vesting conditions, expense is recognized using the accelerated attribution method when the performance condition is deemed to be probable of being satisfied. The Company accounts for forfeitures as they occur. The Company determines the fair value of restricted stock awards in reference to the fair value of its common stock less any applicable purchase price.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option and the Company's expected dividend yield. As there is no public market for its common stock, the Company determines the volatility for awards granted based on an analysis of reported data for a group of guideline companies that have issued options with substantially similar terms. The expected volatility has been determined using a weighted-average of the historical volatility measures of this group of guideline companies. The Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options granted to employees has been determined utilizing the "simplified" method, using the midpoint between the vesting date and the contractual term. 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. The Company has not paid, and does not anticipate paying, cash dividends on its common stock; therefore, the expected dividend yield is assumed to be zero.

The Company classifies stock-based compensation expense in its statements of operations and comprehensive loss in the same manner in which the award recipient's cash compensation costs are classified.

***Determination of the Fair Value of Common Stock***

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. The Company has utilized various valuation 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 (the "Practice Aid"), to estimate the fair value of its common stock. The common stock valuation is based on the Company's enterprise value determined utilizing various methods including the option-pricing method ("OPM") or a hybrid of the probability-weighted expected return method ("PWERM") and the OPM. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

***Warrants***

The Company accounts for warrants on capital stock based on guidelines provided in ASC Topic 815, Derivatives and Hedging—Contracts in Entity's Own Equity ("ASC 815"), which provides guidance on contracts that are settled in the Company's own shares as either a liability or as an equity instrument depending on the warrant agreement. The Company uses the Black-Scholes pricing model, depending on the applicable terms of the warrant agreement, to value the warrants.

***Net Loss per Share***

Net loss per share attributable to common stockholders is computed by using the two-class method, which is an earnings allocation formula that determines loss per share for the holders of the Company's common stock and participating securities. All series of preferred stock contain participation rights in any dividend declared or accumulated by the Company and are deemed to be participating securities. Income available to common stockholders and participating convertible preferred stock is allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. The participating securities do not include a contractual obligation to share in losses of the Company and are not included in the calculation of net loss per share in the periods that have a net loss.

Diluted net income per share is computed using the more dilutive of (a) the two-class method, or (b) the if-converted method. The Company allocates earnings first to preferred stockholders based on dividend rights and then to common and preferred stockholders based on ownership interests. The weighted-average number of common stock included in the computation of diluted loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, and convertible preferred stock. Common stock equivalent shares are excluded from the computation of diluted loss per share if their effect is antidilutive.

The Company's convertible preferred stock contractually entitles the holders of such shares to participate in dividends. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss to common stockholders for the years ended December 31, 2020 and 2019, respectively.

### **Comprehensive Loss**

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. For the years ended December 31, 2020 and 2019, comprehensive loss was equal to net loss.

### **Recently Adopted Accounting Pronouncements**

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement* (“ASU 2018-13”). The new standard removes certain disclosures, modifies certain disclosures and adds additional disclosures related to fair value measurement. The Company adopted this pronouncement on January 1, 2020, which did not have a material impact on the Company’s financial statements.

### **Recently Issued Accounting Pronouncements Not Yet Adopted**

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* (“ASC 842”), which amends the existing accounting standards for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. In July 2018, the FASB issued additional guidance, which offers a transition option to entities adopting the new lease standard. Under the transition option, entities can elect to apply the new guidance using a modified retrospective approach at the beginning of the year in which the new lease standard is adopted, rather than to the earliest comparative period presented in their financial statement and provides for certain practical expedients. The guidance is effective for reporting periods beginning after December 15, 2020 for private companies with early adoption permitted.

The Company has completed its assessment of the impact ASU 2016-02 will have on its financial position, results of operations, and related footnotes. The adoption of the new standard will result in the recognition of right-of-use assets and lease liabilities of approximately \$0.5 million and \$0.6 million, respectively, on the Company’s balance sheet as of January 1, 2021.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments — Credit Losses (Topic 362): Measurement of Credit Losses on Financial Statements* (“ASU 2016-13”). The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The targeted transition relief standard allows filers an option to irrevocably elect the fair value option of ASC 825-10, *Financial Instruments-Overall*, applied on an instrument-by-instrument basis for eligible instruments. For public entities that are Securities and Exchange Commission (“SEC”) filers, excluding entities eligible to be smaller reporting companies, ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. For all other entities, ASU 2016-13 is effective for annual periods beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. The Company does not expect this standard to have a material impact on its financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes-Simplifying the Accounting for Income Taxes* (“ASU 2019-12”). ASU 2019-12 eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard is effective for annual periods beginning after December 15, 2020 and interim periods within, with early adoption permitted. Adoption of the standard requires certain changes to be made prospectively, with some

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changes to be made retrospectively. The Company is currently assessing the impact of this standard on its financial statements.

### 3. Fair Value of Assets and Liabilities

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2020 and December 31, 2019 (in thousands):

Description	December 31, 2020	Quoted prices active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant other observable inputs (Level 3)
<i>Liability</i>				
Warrant Liability	\$ 72	\$ —	\$ —	\$ 72
Total financial liabilities	<u>\$ 72</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 72</u>

Description	December 31, 2019	Quoted prices active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant other observable inputs (Level 3)
<i>Liability</i>				
Warrant Liability	\$ 75	\$ —	\$ —	\$ 75
Total financial liabilities	<u>\$ 75</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 75</u>

At December 31, 2020, the fair value of the warrant liability was determined based on Level 3 inputs and utilizing the Black-Scholes option pricing model (see Note 10).

During the years ended December 31, 2020 and 2019, there were no transfers into or out of Level 3.

The following table set forth a summary of changes in the fair value of the ("Series B Warrants"), which represents a recurring fair value measurement that is classified within Level 3 of the fair value hierarchy. Changes in fair value are recognized in other (expense) income as "Change in fair value of warrant liability" in the Company's statements of operations and comprehensive loss (in thousands):

<u>Series B Warrants (173,827 warrants)</u>	
Fair value at December 31, 2018	\$31
Change in fair value	<u>44</u>
Fair value at December 31, 2019	<u>75</u>
Change in fair value	<u>(3)</u>
Fair value at December 31, 2020	<u>\$72</u>

#### 4. Property and Equipment, Net

At December 31, 2020 and 2019, property and equipment consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Assets under construction	\$ 1,154	\$ 1,203
Equipment capital lease	97	97
Lab equipment	4,611	3,788
Office furniture	64	64
	<u>\$ 5,926</u>	<u>\$ 5,152</u>
Less—accumulated depreciation	(2,352)	(1,518)
Property and equipment, net	<u>\$ 3,574</u>	<u>\$ 3,634</u>

For the years ended December 31, 2020 and 2019, depreciation expense was \$0.8 million and \$0.5 million, respectively. For the years ended December 31, 2020 and 2019, \$0.02 million of depreciation expense was attributable to the equipment capital lease.

#### 5. Prepaid Expenses and Other Current Assets

At December 31, 2020 and 2019, prepaid expenses and other current assets consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Prepaid insurance	\$ 51	\$ 45
Prepaid research and development expenses	915	777
Prepaid license agreements	61	—
Other	16	56
Prepaid expenses and other current assets	<u>\$ 1,043</u>	<u>\$ 878</u>

#### 6. Accrued Expenses and Other Current Liabilities

At December 31, 2020 and 2019, accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Accrued research and development expenses	\$ 750	\$ 2,114
Accrued compensation	1,023	1,297
Other	262	405
Accrued expenses and other current liabilities	<u>\$ 2,035</u>	<u>\$ 3,816</u>

#### 7. Convertible Preferred Stock

As of December 31, 2020, the Company had 1,701,141 authorized, issued and outstanding shares of Series A convertible preferred stock ("Series A"), 3,298,732 authorized, issued and outstanding shares of Series A-1 convertible preferred stock ("Series A-1"), 4,325,021 authorized shares and 4,324,998 issued and outstanding shares of Series A-2 convertible preferred stock ("Series A-2") and, 22,705,646 authorized shares and 22,531,819 issued and outstanding shares of Series B convertible preferred stock ("Series B"), 58,109,711 authorized, issued and outstanding shares of Series C-1

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convertible preferred stock ("Series C-1"), 33,218,192 authorized, issued and outstanding shares of Series C-2 convertible preferred stock ("Series C-2", together with Series C-1, "Series C"), 57,878,742 authorized, issued and outstanding shares of Series D-1 convertible preferred stock ("Series D-1") and 24,598,481 authorized shares and 14,469,710 issued and outstanding shares of Series D-2 convertible preferred stock ("Series D-2", together with Series D-1, "Series D," and together with the Series C and Series B, collectively the "Senior Preferred Stock"). All series of convertible preferred stock are collectively referred to as Preferred Stock, each with a par value of \$0.00001 per share.

As of December 31, 2019, the Company had 1,710,141 authorized, issued and outstanding shares of Series A stock, 3,298,732 authorized, issued and outstanding shares of Series A-1 stock, 4,325,021 authorized shares and 4,324,998 issued and outstanding shares of Series A-2 stock, 22,705,646 authorized shares and 22,531,819 issued and outstanding shares of Series B stock, 58,109,711 authorized, issued and outstanding shares of Series C-1 stock, 33,218,192 authorized, issued and outstanding shares of Series C-2 stock, and 57,878,742 authorized, issued and outstanding shares of Series D stock, each with a par value of \$0.00001 per share.

### **Series D-2 Offering**

On June 25, 2020, the Company entered into the Series D-2 Purchase Agreement ("Series D-2 Agreement") with certain investors to sell up to 24,598,481 shares of Series D-2 stock at a purchase price of \$0.6911 per share. The Series D-2 Agreement provides for two closings, the first on October 1, 2020 and the second upon the achievement or waiver of certain milestone events. The Company sold 14,469,710 shares of Series D-2 stock on October 1, 2020 at the first tranche closing for gross proceeds of \$10.0 million. The second tranche closing, contingent upon the achievement or waiver of certain milestones, has occurred in 2021 (see Note 16).

Costs incurred in connection with the Series D-2 offering totaled \$0.1 million during the year ended December 31, 2020 and were recorded as a reduction to Series D-2 convertible preferred stock.

The Company evaluated the tranche rights pursuant to the Series D-2 Agreement and determined the tranche rights did not represent a freestanding financial instrument as they are not legally detachable from the Series D-2 shares issued in the first tranche.

The rights and privileges of the Company's Preferred Stock are as follows:

### **Voting**

Except as otherwise required by law or by other provisions, holders of the Preferred Stock vote together with the holders of common stock as a single class. Holders of Preferred Stock may cast the number of votes equal to the number of shares of common stock to which such shares of Preferred Stock are convertible into.

### **Dividends**

#### *Series C and D Dividends:*

From and after the date of the issuance of any shares of Series C-1, Series C-2, Series D-1 and Series D-2, dividends at the annual rate of seven percent (7%) per annum of the original share price per share accrue on such shares of Series C-1, Series C-2, Series D-1, and Series D-2. Dividends accrue from day to day, whether or not declared, and are cumulative, but not compounding. Such dividends are only payable when and if declared by the Board or in the event of a Deemed Liquidation Event (as defined in the amended and restated Certificate of Incorporation). No other dividends may be declared or paid on any other class of stock unless the holders of the shares of Series D then outstanding first receive, or simultaneously receive, their applicable dividend. For the year ended December 31, 2020, \$5.9 million, \$2.6 million, \$3.9 million and \$0.2 million of cumulative dividends on Series C-1, Series C-2, Series D-1 and Series D-2, respectively, are included in the liquidation preference amount indicated on the balance sheet.

*Series B Dividends:*

From and after the date of the issuance of any shares of Series B, dividends at the annual rate of \$0.0869645 per share accrue on such shares of Series B. Dividends accrue from day to day, whether or not declared, and are cumulative, but not compounding. Such dividends are only payable when and if declared by the Company's Board or in the event of a Deemed Liquidation Event (as defined in the amended and restated Certificate of Incorporation). No other dividends may be declared or paid on any other class of stock unless the holders of the shares of Series B then outstanding first receive, or simultaneously receive, their applicable dividend. For the year ended December 31, 2020, \$9.4 million of cumulative dividends on Series B are included in the liquidation preference amount indicated on the balance sheet.

*Series A Dividends*

From and after the date of the issuance of Series A, Series A-1, and Series A-2, if the Company declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Company, the dividend payable to the holders of Series A, Series A-1, and Series A-2 convertible preferred stock shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest dividend. No other dividends, or dividends on common stock payable in shares of common stock, may be declared or paid unless the holders of Series A, Series A-1, and Series A-2 then outstanding first receive, or simultaneously receive, their applicable dividend. As of December 31, 2020, no dividends have been declared on the common stock or the convertible preferred stock.

**Liquidation Rights**

In the event of a Deemed Liquidation Event, as defined in the Company's amended and restated Certificate of Incorporation, the assets of the Company will be distributed first to the holders of Series D. The holders of Series D will receive, in preference to all other stockholders, an amount equal to the sum of the Series D original issue price (equal to the cash price paid per share of \$0.6911), plus unpaid dividends on such shares. Next, the holders of Series C will receive, in preference to all stockholders other than the Series D holders, an amount equal to the sum of the Series C original issue price plus unpaid dividends on such shares. Next, the holders of Series B will receive, in preference to the holders of Series A, Series A-1, Series A-2 and common stock, an amount equal to the sum of the Series B original issue price plus unpaid dividends on such shares. Next, the holders of Series A, Series A-1, and Series A-2 will receive, in preference to the holders of common stock, an amount equal to the greater of their applicable liquidation preference or what they would have received had their shares converted into common stock. If the proceeds available are not sufficient to satisfy the full liquidation preference, the entire proceeds are to be distributed pro-rata among the Series D holders in proportion to the full preferential amount the Series D holders are entitled to receive.

**Conversion**

The Senior Preferred Stock converts into common stock on a one-for-one basis. Each share of Series B, Series C-1, Series C-2, Series D-1, and Series D-2 is convertible into the number of shares of common stock as is determined by dividing the respective original issue price by the conversion price in effect at the time of conversion. The Series D-1 and Series D-2 conversion price is set at \$0.6911 per share, Series C-1 conversion price is set at \$0.5213 per share, the Series C-2 conversion price is set at \$0.36491 per share and the Series B conversion price is set at \$1.24235 per share; none represents a beneficial conversion feature. Subject to certain exceptions, the Senior Preferred Stock has the benefit of anti-dilution protection on a weighted-average basis in the event that the Company sells stock at less than the applicable conversion price per share.

Each share of Series A and Series A-1 was originally convertible into the number of shares of common stock determined by dividing the respective Series A and Series A-1 original issue price by the conversion price in effect at the time of conversion. The Series A conversion price was originally equal to \$2.00 per share and the Series A-1 conversion price was originally equal to \$2.4847 per

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share. As Series A-2 was sold at \$1.24235 per share, less than the per share prices of Series A and Series A-1, anti-dilution protections were triggered. Pursuant to the anti-dilution protection terms, on February 24, 2015, the Series A conversion price was reduced from \$2.00 to \$1.8191 per share of common stock and the Series A-1 conversion price was reduced from \$2.4847 to \$2.1898 per share of common stock and, therefore, the Series A conversion ratio was changed from 1:1 to 1:1.099 and the Series A-1 conversion ratio was changed from 1:1 to 1:1.135. The Company evaluated Series A and Series A-1 with the updated conversion ratios and determined that there was no beneficial conversion feature.

Series A-2 converts into common stock on a one-for-one basis. The Series A-2 conversion price is set at \$1.24235 per share and does not represent a beneficial conversion feature.

According to the terms of the Company's amended and restated certificate of incorporation, in the event that the applicable conversion price for any series of Senior Preferred Stock is reduced, then the applicable conversion price for each series of Series A convertible preferred stock shall be uniformly and concurrently reduced.

Each share of Preferred Stock will automatically convert into common stock upon (a) the occurrence of an event, specified by vote or written consent of certain stockholders or (b) the completion of a public stock offering involving a price per share of common stock of not less than \$1.554975 per share, subject to certain adjustments, where such offering results in aggregate gross proceeds to the Company of at least \$50.0 million and the common stock is listed for trading on either the New York Stock Exchange or the Nasdaq Stock Market.

The Company must reserve and keep available out of its authorized but unused capital stock such number of authorized shares of common stock to sufficiently effect the conversion of all outstanding Preferred Stock.

In considering the features of the convertible preferred stock, the Company determined that none of the features, including the conversion features, requires bifurcation during 2020 and 2019.

The conversion ratios for the Series A stock was changed to 13.700 to 1.099, Series A-1 stock was changed to 13.7 to 1.135, and the Series A-2 stock through Series E stock was changed to 13.7 to 1 upon the Company's filing of its amendment to its Amended and Restated Certificate of Incorporation on October 22, 2021 (see Note 16(E)).

## **8. Common Stock**

The Company has 232,697,999 and 208,099,518 authorized shares of common stock, par value \$0.00001 per share, of which 381,123 and 340,591 shares were issued and outstanding as of December 31, 2020 and 2019, respectively.

## **9. Stock-Based Compensation**

On January 15, 2009, the Company's Board adopted the 2009 Long-Term Incentive Stock Option Plan (the "2009 Plan") for the issuance of stock-based compensation to both employees and non-employees. The awards under this plan typically vest over a 24, 36 or 48-month period depending on the option agreement and have a 10-year term. On December 12, 2018, the 2009 Plan expired, and the Company adopted the Aura Biosciences, Inc. 2018 Equity Incentive Plan (the "2018 Plan" and collectively with the 2009 Plan, "the Plans"). No options were modified in conjunction with the expiration of the 2009 Plan. The options granted under the 2009 Plan continue to be outstanding in accordance with their original terms. The 2018 Plan will expire in 2028. Under the 2018 Plan, Aura may grant incentive stock options, non-qualified stock options, restricted and unrestricted stock awards and stock rights.



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The Board is authorized to administer the 2018 Plan. In accordance with the provisions of the 2018 Plan, the Board determines the terms of Aura options and other awards issued pursuant thereto, including the following:

- which employees, directors and consultants shall be granted awards;
- the number of shares of common stock subject to options and other awards;
- the exercise price of each option, which generally shall not be less than fair market value of the common stock on the date of grant;
- the termination or cancellation provisions applicable to options;
- the terms and conditions of other awards, including conditions for repurchase, termination or cancellation, issue price and repurchase price; and
- all other terms and conditions upon which each award may be granted in accordance with the 2018 Plan.

In addition, the Board or any committee to which the Board delegates authority may, with the consent of the affected plan participants, re-price or otherwise amend outstanding awards consistent with the terms of the 2018 Plan. On December 12, 2018, the Board approved an increase to the 2018 Plan available option pool of 3,778 options. With this increase and the transfer of the available options from the 2009 Plan, there were 22,626 options available for grant under the 2018 Plan at December 31, 2020.

The following table summarizes stock option activity under the 2018 Plan for the year ended December 31, 2020:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	1,246,142	\$ 3.70	8.03	1,111
Granted	465,544	\$ 4.25		
Exercised	(40,529)	\$ 4.11		
Cancelled/Forfeited	(159,028)	\$ 3.97		
Outstanding at December 31, 2020	<u>1,512,129</u>	<u>\$ 3.84</u>	<u>7.77</u>	<u>1,174</u>
Exercisable at December 31, 2020	<u>761,013</u>	<u>\$ 3.84</u>	<u>6.81</u>	<u>755</u>

The weighted-average grant date fair value of stock options granted during the years ended December 31, 2020 and 2019 was \$2.74 and \$2.47 per share, respectively. The total intrinsic value of options exercised was \$0.02 million and \$0 for the years ended December 31, 2020 and 2019, respectively.

Further, the total fair value of stock options vested during the years ended December 31, 2020 and 2019 was \$0.7 million and \$0.5 million, respectively.

The Company has elected to use the Black-Scholes option pricing model to determine the fair value of options granted and generally recognizes the compensation cost of stock-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of stock-based payment awards utilizing the Black-Scholes option pricing model is affected by the estimated fair value of the Company's common stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate, and expected dividends.

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The fair value of the stock options issued as of December 31, 2020 and 2019 was measured with the following weighted-average assumptions:

	December 31, 2020	December 31, 2019
Risk-free interest rate	0.55%	2.05%
Expected term	6.02	6.02
Expected volatility of the underlying stock	74.04%	76.52%
Expected dividend rate	0%	0%

The Company recorded stock-based compensation as follows (in thousands):

	December 31, 2020	December 31, 2019
Research and development	\$ 193	\$ 182
General and administrative	543	325
Total	<u>\$ 736</u>	<u>\$ 507</u>

As of December 31, 2020, there was \$1.9 million of unrecognized compensation expense related to stock options, which is expected to be recognized over a weighted-average period of 1.89 years.

### 10. Series B Warrants

In February 2015 and May 2015, the Company issued warrants to purchase 1,650,098 and 887,536 shares of Series B convertible preferred stock, respectively, at an exercise price of \$1.24235 per share. Each Series B Warrant was immediately exercisable and expires ten years from the original date of issuance. Pursuant to FASB ASC Topic 480, *Distinguishing Liabilities from Equity*, the Series B Warrants were classified as a liability and are re-measured to fair value at each balance sheet date and immediately prior to exercise.

A total of 173,827 of the Series B Warrants remained outstanding at December 31, 2020 and 2019.

The warrants were valued using the Black-Scholes option pricing model. The estimated fair value of the warrants and the significant assumptions used were as follows:

<u>Series B Warrants</u>	<u>December 31, 2020</u>	<u>December 31, 2019</u>
Series B estimated fair value	\$ 1.17	\$ 1.16
Volatility	74%	75%
Expected term (years)	4.2	5.2
Risk free rate	0.27%	1.69%
Dividend yield	7.00%	7.00%

### 11. Compensation

In January 2012, the Company adopted the Aura Biosciences 401(K) Profit Sharing Plan and Trust (the "401(k) Plan") for its employees, which is designed to be qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the 401(k) Plan within statutory and 401(k) Plan limits. The Company makes matching contributions of 100% of the first 6% of employee contributions. The Company made matching contributions in the amount of \$0.2 million and \$0.2 million for the years ended December 31, 2020 and 2019, respectively.

## 12. Commitments and Contingencies

### **Lease Commitments**

The Company leases its facility under a non-cancelable operating lease and there is a security deposit of \$0.1 million held by the lessor.

The Company recognizes rent expense, including escalation charges, on a straight-line basis.

On October 17, 2019, the Company executed an amendment to the facility lease to extend the lease term by a period of 30 months from February 1, 2020 to July 31, 2022.

Rent expense under this operating lease was \$0.3 million for each of the years ended December 31, 2020 and 2019.

Future minimum payments under the remaining term of the lease as of December 31, 2020, are as follows (in thousands):

	<b>Amounts</b>
2021	\$ 360
2022	211
2023	—
2024	—
2025	—
Total minimum payments	<u>\$ 571</u>

### **Laser Purchasing Commitment**

On April 5, 2019, the Company entered into a purchase agreement for equipment with future commitments payable in three installments of €0.2 million each. The first two installments of €0.2 million were paid by the Company in April 2019 and August 2019, respectively. The last installment of €0.2 million will be due upon shipment of the initial order, which is expected to occur in 2021. The Company will receive 20 laser systems upon completion of the final installment payment. Upon receipt of the laser systems, the Company will assess whether the laser systems have an alternative future use and, if so, will capitalize the lasers as a component of fixed assets.

### **License Agreements**

The Company has entered into the following key agreements that relate to the core technology under development:

#### *LI-COR Exclusive License and Supply Agreement*

In January 2014, the Company entered into an Exclusive License and Supply Agreement, or the LI-COR Exclusive License Agreement with LI-COR, Inc. ("LI-COR") for the license of IRDye 700DX and related licensed patents for the treatment and diagnosis of ocular cancers in humans, and as amended in January 2016, July 2017, April 2018 and April 2019. LI-COR is a related party owning shares of the Company's capital stock. The LI-COR Exclusive License Agreement required a one-time upfront license issue fee of \$0.1 million and requires aggregate milestone payments of up to \$0.2 million upon certain regulatory and development milestones. The Company is also required to pay LI-COR low-single digit royalties on net sales. The term of the LI-COR Exclusive Agreement expires on a country-by-country basis, until the longer of (i) ten years from the first commercial sale of a licensed product in such country and (ii) the last to expire valid claim in such country. The Company recognized \$0.2 million and \$0.8 million of expenses related to this agreement and related amendments for the years ended December 31, 2020 and 2019, respectively.

*LI-COR Non-Exclusive License and Supply Agreement*

In December 2014, the Company entered into a Non-Exclusive License Agreement (the “2014 Non- Exclusive Agreement”) for LI-COR to supply IRDye 700DX to the Company for the treatment and diagnosis of non-ocular cancers in humans. Under the 2014 Non-Exclusive Agreement, the Company paid a license issue fee of \$0.03 million on the effective date. The Company must also pay LI-COR a non-refundable, non-creditable fee of \$0.03 million per each licensed product upon pre-IND designation, as defined, of such licensed product. During the term, the Company must pay LI-COR a low-single digit percentage royalty on net sales. LI-COR receives 10% of all sublicensee income within 30 days of the Company’s receipt from the sublicensee. The 2014 Non-Exclusive Agreement also required the Company to make certain payments upon the achievement of specified development and commercial milestones of up to \$0.4 million in the aggregate.

*Life Technologies Corporation*

In December 2014, the Company entered into a non-exclusive, perpetual license agreement with Life Technologies Corporation (“Life Technologies”), which allows for five licensed products. Under this agreement the Company is required to pay an initial license fee of \$0.1 million for each product. An annual development fee of \$0.1 million is due within a year from the payment of the initial license fee and due annually until the earlier of (i) payment of a commercialization fee or (ii) all development work is terminated. The commercialization fee is a one-time, non-refundable, non-creditable fee of \$0.3 million due upon receipt of approval of a licensed product. In the event of a change of control, there will be a change of control fee of \$0.2 million. During each of the years ended December 31, 2020 and 2019, the Company recognized \$0.1 million of expenses related to this agreement.

*National Institute of Health (NIH)-Biologic Materials License Agreement*

In December 2010, the Company entered into a Biologic Materials License Agreement with National Institutes of Health (the “NIH”) for a non-exclusive right to use materials described in Schiller et al., *Virology* 2004 Apr.10, 321(2):205-16, which required a one-time non-refundable license issuance fee of \$0.02 million. No future milestone payments or royalties are due under this agreement.

*National Institute of Health (NIH)-Collaboration Research and Development Agreement*

In July 2011, the Company entered into a Collaboration Research and Development Agreement (“CRADA”) with Dr. John Schiller at the NIH, for a period of two years with the rights to an exclusive license to all technology generated within the collaboration. Under the agreement, the Company was required to make annual payments each year to fund the research activities, with the first payment due within 30 days of the effective date and subsequent payments due within 30 days of the anniversary date. This agreement was further amended in 2012, 2013, 2014, 2015, 2016, 2018 and most recently in September of 2020. From 2011-2020, the Company paid an aggregate of \$0.3 million in research collaboration fees, \$0.04 million of which was paid in 2020 and \$0.04 million was paid in 2019.

In September 2020, the Company executed the seventh amendment to the CRADA agreement. In this amendment the term of this agreement is extended until September 30, 2022, and the Company must pay \$0.03 million on the tenth anniversary of the CRADA agreement which will occur in September of 2021.

*National Institute of Health (NIH)-Exclusive Patent License Agreement*

In 2013, the Company entered into an exclusive patent license agreement (the “NIH Exclusive License Agreement”) with the NIH that required the Company to pay a license issue royalty fee of \$0.1 million and reimburse the NIH for any patent expenses incurred. Under the agreement, the Company is required to make low single-digit percentage royalty payments based on specified levels of annual net sales of licensed products subject to certain specified reductions. The Company is required to make development and regulatory milestone payments up to \$0.7 million in the aggregate and sales milestone payments up to \$0.6 million in the aggregate. The Company is also required to pay NIH a mid-single to low teen-digit percentage of any sublicensing revenue the Company receives. Additionally, the Company’s payment obligations to NIH are subject to an annual minimum royalty

payment of low five figures. As of December 31, 2020, the Company has paid NIH approximately \$0.3 million in aggregate milestones under the NIH Exclusive License Agreement. In addition to milestones under the agreement, the Company reimburses the NIH for any patent prosecution costs incurred. As of December 31, 2020, the Company has reimbursed the NIH approximately \$0.3 million in aggregate. The Company accrued \$0.02 million and \$0.02 million in patent licensing reimbursement fees for 2020 and 2019, respectively.

*Inserm*

In November 2009, the Company entered into an exclusive, royalty-bearing license agreement with Inserm-Transfert of France for use of its patents. The agreement expires on a country by country basis based on the last to expire of any patent encompassed within the scope of the patent rights or 10 years from the date of the first commercial sale by the Company, whichever is later. There are potential milestone payments of up to €0.5 million (up to \$0.5 million at December 31, 2020) in the aggregate associated with this agreement. The IND filing milestone of €0.01 million was accrued in 2016 and paid in 2017 by the Company. The milestones for the successful Phase I, II and III clinical trials are based on receiving a final report and achieving the primary endpoints defined in that trial and those milestones have not been achieved as of December 31, 2020. Upon the sublicense by the Company of a product for which royalties are payable under this agreement, low- to mid-single-digit royalty payments would be due by the Company. If the Company sublicenses the delivery platform for use with multiple drugs, low- to mid-teen payments on receipts would be due by the Company. The non-milestone payments in this agreement are subject to an anti-stacking clause. The Company did not incur any expense in the years ended December 31, 2020 and 2019.

*Clearside*

In July 2019, the Company entered into a License Agreement with Clearside Biomedical, Inc. ("Clearside") for the license of Clearside's Suprachoroidal Microneedle Technology for use in an upcoming clinical trial expected to begin in 2020. Upon execution of the License Agreement, the Company paid Clearside an upfront payment of \$0.1 million which was expensed as incurred. Under the Clearside License Agreement, the Company is required to pay milestones up to \$21.0 million in the aggregate to Clearside upon the achievement of specified regulatory and development milestones, and upon the achievement of certain commercial sales milestones. The Company is also required to pay low to mid-single digit royalties on net sales. If the Company sublicenses a product for which royalties are payable, then the Company is required to pay the greater of 20% received or low single digit royalties on net sales.

The Clearside License Agreement expires on a country-by-country basis upon the later of the last to expire patent or ten years from the date of the first commercial sale of a product.

### **13. Net Loss Per Share**

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is the same as basic net loss per share for the periods presented since the effects of potentially dilutive securities are antidilutive given the net loss of the Company.

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The Company has calculated basic and diluted loss per share for the years ended December 31, 2020 and 2019 as follows (in thousands, except share and per share data):

	December 31, 2020	December 31, 2019
Numerator:		
Net loss	\$ (22,206)	\$ (24,200)
Less: Accruals of dividends of preferred stock	(7,926)	(6,029)
Net loss attributable to common stockholders—basic and diluted	<u>\$ (30,132)</u>	<u>\$ (30,229)</u>
Denominator:		
Weighted-average common stock outstanding	367,204	338,289
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (82.06)</u>	<u>\$ (89.36)</u>

The following potentially dilutive securities were excluded from the computation of the diluted net loss per share for the periods presented because their effect would have been antidilutive:

	December 31, 2020	December 31, 2019
Convertible preferred stock on an if converted basis	14,317,032	13,260,868
Stock options to purchase common stock	1,512,129	1,246,142
Warrants to purchase preferred stock	12,686	12,686
Total potential dilutive shares	<u>15,841,847</u>	<u>14,519,696</u>

## 14. Income Taxes

The Company has not recorded any net tax provision for the periods presented due to the losses incurred and the need for a full valuation allowance on net deferred tax assets. The difference between the income tax expense at the U.S. federal statutory rate and the recorded provision is primarily due to the valuation allowance provided on all deferred tax assets. The Company's loss before income tax for the periods presented was generated entirely in the United States:

A reconciliation of the federal statutory income tax rate to the Company's effective tax rate as of December 31, 2020 and 2019 is as follows:

	2020	2019
Tax provision at statutory rate	21.0%	21.0%
State taxes, net of federal benefit	5.4%	5.6%
Federal tax credits	3.8%	4.1%
Permanent Items	(0.3)%	(0.4)%
Other	(0.4)%	(1.3)%
US tax rate change	0.0%	0.0%
Decrease in valuation reserve	(29.5)%	(29.1)%
Total	<u>0.0%</u>	<u>0.0%</u>

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Temporary differences that give rise to significant deferred tax assets (liabilities) as of December 31, 2020 and 2019 are as follows (in thousands):

	<u>2020</u>	<u>2019</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 27,921	\$ 21,434
Stock-based compensation expense	328	252
Capitalized research and development expenses	–	23
Tax credit carryforwards	4,675	3,739
Accrued expenses	418	1,394
Other	168	84
Total deferred tax assets	<u>33,510</u>	<u>26,926</u>
Depreciable Assets	(157)	(110)
Valuation allowance	<u>(33,353)</u>	<u>(26,816)</u>
Net deferred tax asset	<u>\$ –</u>	<u>\$ –</u>

As of December 31, 2020, the Company had federal gross operating loss carryforwards of approximately \$106.1 million which may be available to offset future taxable income, of which \$44.2 million begin to expire in 2029 and go through 2037 and \$61.9 million do not expire. The Company had state gross operating loss carryforwards of \$89.3 million, which may be available to offset future taxable income, and which would begin to expire in 2030. As of December 31, 2020, the Company had federal and state research and experimentation credit carryforwards of \$3.8 million and \$1.1 million, respectively, which may be available to offset future income tax liabilities and which would begin to expire in 2029 and 2027, respectively.

The Company's ability to use its operating loss carryforwards and tax credit carryforwards to offset taxable income is subject to restrictions under Sections 382 and 383 of the United States Internal Revenue Code (the "Internal Revenue Code"). Under the Internal Revenue Code provisions, certain substantial changes in the Company's ownership, including the sale of the Company or significant changes in ownership due to sales of equity, have limited and may limit in the future, the amount of net operating loss carryforwards which could be used annually to offset future taxable income. The Company has not yet completed an analysis of ownership changes. The Company may also experience ownership changes in the future as a result of subsequent shifts in its stock ownership, some of which may be outside the Company's control. As a result, the Company's ability to use its pre-change NOLs to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to the Company. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. All Federal NOLs generated post tax reform have an indefinite life, are not subject to carryback provisions, and limited to 80% of income in any year.

The Company has not conducted a study of its research and development credit carryforwards. A study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed, and any adjustment is known, no amounts will be presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credit carryforwards and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations at this time, if an adjustment were required.

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Management has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are principally comprised of NOL carryforwards and tax credit carryforwards. Management has determined that it is more likely than not that the Company will not realize the benefits of its deferred tax assets, and as a result, a valuation allowance of \$33.4 million has been recorded at December 31, 2020. The increase in the valuation allowance of \$6.6 million during the year ended December 31, 2020 was primarily due to the increase in net operating loss generated by the Company.

As of December 31, 2020, and 2019, the Company had no unrecognized tax benefits. The Company does not expect any significant change in its uncertain tax positions in the next twelve months.

The Company files income tax returns in the United States federal tax jurisdiction and several state tax jurisdictions. Since the Company is in a loss carryforward position, it is generally subject to examination by federal and state tax authorities for all tax years in which a loss carryforward is available.

### **15. Related Parties**

During 2020 and 2019, the Company incurred \$0 and \$0.3 million in expenses to a legal firm whose partner is also an investor and former officer of the Company. As of December 31, 2020, and 2019, none of these amounts were included in accounts payable.

During 2020 and 2019, the Company incurred \$0.5 million and \$0.3 million in expenses to a stockholder that provided research and development related services. Of these amounts, \$0.1 million and \$0.01 million were in accrued expenses as of December 31, 2020 and 2019, respectively.

During 2020 and 2019, two members of the Board received compensation from the Company while also consulting for other equity stockholders. Payment to the members was \$0.1 million in 2020 and \$0.02 million in 2019. The Board members resigned from the Board in September of 2019 and March of 2021.

During 2020 and 2019, the Company incurred \$0.01 million and \$0.01 million in expense to a consultant who is also a spouse of an employee at the Company. As of December 31, 2020, and 2019, de minimis amounts were included in accounts payable.

### **16. Subsequent Events**

The Company has evaluated subsequent events from the balance sheet date through the filing date of this Registration Statement on Form S-1, and identified the following subsequent events:

#### **A. Convertible Preferred Stock**

On March 5, 2021, the Company completed the second tranche of Series D-2 offering and issued 10,128,771 shares of Series D-2 Stock, \$0.00001 par value per share, at a purchase price of \$0.6911 per share for aggregate proceeds of \$7.0 million.

On March 18, 2021, the Company completed its Series E Stock offering and issued 102,671,041 shares of Series E Stock, \$0.00001 par value per share, at a purchase price of \$0.7839 per share for aggregate proceeds of \$80.5 million.

#### **B. Cambridge Lease Modification**

On March 31, 2021, the Company executed an amendment to the facility lease which included an extension of the expiration date of the original leased premises, the addition of 4,516 square feet of laboratory space with an expected commencement date of May 1, 2021, and the addition of 1,000



square feet of laboratory space with an expected commencement date of June 15, 2021. The lease term for the original and new spaces will expire on July 31, 2023, with an option to renew for an additional 12 months.

**C. Stock-based compensation (unaudited)**

On March 18, 2021, the Company's 2018 Plan was amended to increase the number of shares of common stock reserved for issuance under the 2018 Plan from 1,670,871 shares to 4,017,100 shares in the aggregate.

From January 1, 2021 through August 9, 2021, the board of directors approved and granted stock options to purchase 1,583,854 shares of the common stock under the 2018 Plan. 1,556,849 of these stock options vest over four years and 27,005 of these stock options vest over one year with exercise prices ranging from \$4.38 to \$5.48 per share. The weighted-average fair value of these stock options is \$3.56 per share and the related stock compensation expense of these stock options of \$5.6 million will be recognized over a weighted-average period of 3.95 years.

From January 1, 2021 through August 9, 2021, 61,590 stock options were exercised at exercise prices ranging from \$2.74 to \$9.45 per share for gross proceeds of \$0.3 million.

On August 2, 2021, Elisabet de los Pinos, the Company's CEO, exercised options for 3,649 shares of common stock, with an exercise price of \$5.48 per common share.

On October 5, 2021, a holder of the Company's convertible preferred stock exercised options for 2,190 and 1,459 shares of common stock, with exercise prices of \$5.75 and \$5.48 per share of common stock, respectively.

On September 22, 2021, the board of directors approved and granted stock options to purchase 299,626 shares of the common stock under the 2018 Plan. 296,344 of these stock options vest over four years and 3,282 of these stock options vest over one year with exercise prices of \$9.59 per share. The weighted-average fair value of these stock options is \$6.17 per share and the related stock compensation expense of these stock options of \$1.8 million will be recognized over a weighted average period of 3.97 years.

**D. Election of Automatic Conversion of Preferred Stock (unaudited)**

On October 7, 2021, the required convertible preferred stockholders authorized the automatic conversion of all shares of convertible preferred stock in an initial public offering, subject to the price per share of the common stock in the Company's sale of shares of common stock to the public in a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least \$75,000,000 of gross proceeds to the Company and such shares being listed on the Nasdaq Stock Market (the "Public Offering"), being at least \$0.94068 (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock), (ii) subject to and effective upon the closing of the Public Offering and (iii) subject to the Public Offering being consummated no later than February 28, 2022.

**E. Reverse stock split**

On October 22 2021, the Company effected a reverse stock split of the Company's common stock on a 1-for-13.7 basis (the "Reverse Stock Split"). In connection with the Reverse Stock Split, the conversion ratio for the Company's convertible preferred stock was proportionately adjusted such that the common stock issuable upon conversion of such preferred stock was decreased in proportion to the Reverse Stock Split. Accordingly, all common stock share and per share amounts, for all periods presented in these financial statements have been retroactively adjusted, to reflect this reverse stock split and adjustment of the convertible preferred stock conversion ratios.

***F. 2021 Stock Option and Incentive Plan (unaudited)***

The 2021 Stock Option and Incentive Plan (the “2021 Plan”) was adopted by the board of directors on October 7, 2021, approved by the Company’s stockholders on October 22, 2021 and will become effective upon the date immediately preceding the date on which the registration statement of which this prospectus is part is declared effective by the SEC. The 2021 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The number of shares initially reserved for issuance under the 2021 Plan was 3,352,166, which will automatically increase on January 1, 2022 and each January 1 thereafter, by 5% of the outstanding number of shares of common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Company’s compensation committee. The maximum number of shares of common stock that may be issued in the form of incentive stock options shall not exceed the initial limit, cumulatively increased on January 1, 2022 and on each January 1 thereafter by the lesser of the Annual Increase for such year or 3,352,166 shares of common stock.

***G. 2021 Employee Stock Purchase Plan (unaudited)***

The 2021 Employee Stock Purchase Plan (the “ESPP”) was adopted by the board of directors on October 7, 2021, approved by the Company’s stockholders on October 22, 2021 and will become effective upon the date immediately preceding the date on which the registration statement of which this prospectus is part is declared effective by the SEC. A total of 335,217 shares of common stock were initially reserved for issuance under this plan, which will automatically increase on January 1, 2022 and each January 1 thereafter through January 1, 2031, by the least of (i) 335,217 shares of common stock, (ii) 1% of the outstanding number of shares of common stock on the immediately preceding December 31 or (iii) such lesser number of shares of common stock as determined by the administrator of the ESPP.

## Aura Biosciences, Inc.

**Condensed Balance Sheets (Unaudited)**  
(in thousands, except share and per share amounts)

	As of	
	June 30, 2021	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$92,197	\$ 17,393
Restricted cash and deposits	31	19
Prepaid expenses and other current assets	647	1,043
Total current assets	92,875	18,455
Restricted cash and deposits, net of current portion	125	75
Operating lease right of use assets	1,240	–
Property and equipment, net	4,078	3,574
Deferred offering costs	335	–
<b>Total Assets</b>	<b>\$98,653</b>	<b>\$ 22,104</b>
<b>Liabilities, Convertible Preferred Stock, and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	2,417	611
Current portion of operating lease liabilities	601	–
Accrued expenses and other current liabilities	2,298	2,050
Total current liabilities	5,316	2,661
Deferred rent	–	8
Operating lease liabilities, net of current portion	661	–
Warrant liability	71	72
Derivative liability	52	–
<b>Total Liabilities</b>	<b>6,100</b>	<b>2,741</b>
<b>Commitments and Contingencies (Note 12)</b>		
Series A convertible preferred stock, \$0.00001 par value, 1,701,141 shares authorized, issued and outstanding at June 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$3,403 at June 30, 2021 and December 31, 2020, respectively	3,368	3,368
Series A-1 convertible preferred stock, \$0.00001 par value, 3,298,732 shares authorized, issued, and outstanding at June 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$8,196 at June 30, 2021 and December 31, 2020, respectively	7,837	7,837
Series A-2 convertible preferred stock, \$0.00001 par value, 4,325,021 shares authorized, and 4,324,998 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$5,373 at June 30, 2021 and December 31, 2020, respectively	5,373	5,373
Series B convertible preferred stock, \$0.00001 par value, 22,705,646 shares authorized, and 22,531,819 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$38,400 and \$37,429 at June 30, 2021 and December 31, 2020, respectively	20,806	20,806

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	As of	
	June 30, 2021	December 31, 2020
Series C-1 convertible preferred stock, \$0.00001 par value, 58,109,711 shares authorized, issued and outstanding at June 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$37,201 and \$36,150 at June 30, 2021 and December 31, 2020, respectively	29,353	29,353
Series C-2 convertible preferred stock, \$0.00001 par value, 33,218,192 shares authorized, issued and outstanding at June 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$15,118 and \$14,697 at June 30, 2021 and December 31, 2020, respectively	11,746	11,746
Series D-1 convertible preferred stock, \$0.00001 par value, 57,878,742 shares authorized, issued and outstanding at June 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$45,297 and \$43,908 at June 30, 2021 and December 31, 2020, respectively	39,686	39,686
Series D-2 convertible preferred stock, \$0.00001 par value, 24,598,481 shares authorized, and 24,598,481 and 14,469,710 issued and outstanding at June 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$17,682 and \$10,176 at June 30, 2021 and December 31, 2020, respectively	16,889	9,907
Series E convertible preferred stock, \$0.00001 par value, 102,671,041 shares authorized, issued and outstanding at June 30, 2021, and a liquidation preference of \$82,105 at June 30, 2021; no shares authorized, issued or outstanding at December 31, 2020	80,246	—
<b>Stockholders' Deficit:</b>		
Common stock, \$0.00001 par value, 470,183,383 and 232,697,999 shares authorized at June 30, 2021 and December 31, 2020, respectively, and 439,068 and 381,123 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	—	—
Additional paid-in capital	8,914	8,173
Accumulated deficit	(131,665)	(116,886)
<b>Total Stockholders' Deficit</b>	<b>(122,751)</b>	<b>(108,713)</b>
<b>Total Liabilities, Convertible Preferred Stock, and Stockholders' Deficit</b>	<b>\$ 98,653</b>	<b>\$ 22,104</b>

*The accompanying notes are an integral part of these unaudited condensed financial statements.*

**Condensed Statements of Operations and Comprehensive Loss (Unaudited)**  
(in thousands except for share and per share data)

	Six Months Ended June 30,	
	2021	2020
<b>Operating Expenses:</b>		
Research and development	10,817	11,649
General and administrative	3,911	2,017
Total operating expenses	<u>14,728</u>	<u>13,666</u>
Total operating loss	<u>14,728</u>	<u>13,666</u>
Other income (expense):		
Change in fair value of warrant liability	1	—
Change in fair value of derivative liability	(52)	—
Interest income (expense), including amortization of discount	3	(2)
(Loss) gain from disposal of assets	(3)	—
Total other income (expense)	<u>(51)</u>	<u>(2)</u>
Net loss and comprehensive loss	<u>\$ (14,779)</u>	<u>\$ (13,668)</u>
Net loss attributable to common stockholders—basic and diluted (Note 13)	<u>\$ (20,738)</u>	<u>\$ (17,522)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (49.49)</u>	<u>\$ (49.27)</u>
Weighted average common stock outstanding—basic and diluted	<u>419,059</u>	<u>355,657</u>

*The accompanying notes are an integral part of these unaudited condensed financial statements.*

Aura Biosciences, Inc.

Condensed Statements of Convertible Preferred Stock and Stockholders' Deficit (Unaudited)  
(in thousands, except share data)

	Convertible Preferred Stock														Common Stock	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit	
	Series A		Series A-1		Series A-2		Series B		Series C-1 and C-2		Series D-1 and D-2		Series E						
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balance, December 31, 2019	1,701,141	\$ 3,368	3,298,732	\$ 7,837	4,324,998	\$ 5,373	22,531,819	\$ 20,806	91,327,903	\$ 41,099	57,878,742	\$ 39,686	-	-	340,591	-	\$ 7,274	\$ (94,680)	\$ (87,406)
Stock-based compensation expense	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	366	-	366
Stock option exercises	-	-	-	-	-	-	-	-	-	-	-	-	-	-	32,528	-	130	-	130
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	(13,668)	(13,668)
<b>Balance, June 30, 2020</b>	<b>1,701,141</b>	<b>\$ 3,368</b>	<b>3,298,732</b>	<b>\$ 7,837</b>	<b>4,324,998</b>	<b>\$ 5,373</b>	<b>22,531,819</b>	<b>\$ 20,806</b>	<b>91,327,903</b>	<b>\$ 41,099</b>	<b>57,878,742</b>	<b>\$ 39,686</b>	<b>-</b>	<b>-</b>	<b>373,119</b>	<b>-</b>	<b>\$ 7,770</b>	<b>\$ (108,348)</b>	<b>\$ (100,578)</b>
Balance, December 31, 2020	1,701,141	\$ 3,368	3,298,732	\$ 7,837	4,324,998	\$ 5,373	22,531,819	\$ 20,806	91,327,903	\$ 41,099	72,348,452	\$ 49,593	-	-	381,123	-	\$ 8,173	\$ (116,886)	\$ (108,713)
Issuance of Series D Tranche 2, convertible preferred stock, net of issuance costs of \$16	-	-	-	-	-	-	-	-	-	-	10,128,771	6,982	-	-	-	-	-	-	-
Issuance of Series E convertible preferred stock, net of issuance costs of \$237	-	-	-	-	-	-	-	-	-	-	-	-	102,671,041	80,246	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	456	-	456
Stock option exercises	-	-	-	-	-	-	-	-	-	-	-	-	-	-	57,945	-	285	-	285
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	(14,779)	(14,779)
<b>Balance, June 30, 2021</b>	<b>1,701,141</b>	<b>\$ 3,368</b>	<b>3,298,732</b>	<b>\$ 7,837</b>	<b>4,324,998</b>	<b>\$ 5,373</b>	<b>22,531,819</b>	<b>\$ 20,806</b>	<b>91,327,903</b>	<b>\$ 41,099</b>	<b>82,477,223</b>	<b>\$ 56,575</b>	<b>102,671,041</b>	<b>\$ 80,246</b>	<b>439,068</b>	<b>-</b>	<b>\$ 8,914</b>	<b>\$ (131,665)</b>	<b>\$ (122,751)</b>

The accompanying notes are an integral part of these unaudited condensed financial statements.

**Aura Biosciences, Inc.**

**Condensed Statements of Cash Flows (Unaudited)**  
(in thousands)

	<b>Six Months Ended June 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (14,779)	\$ (13,668)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	385	373
Stock-based compensation expense	456	366
Non-cash operating lease expense	2	–
Change in fair value of warrant liability	(1)	–
(Loss) gain on disposal of property and equipment	(3)	–
Change in fair value of derivative liability	52	–
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	396	(204)
Accounts payable	1,612	1,264
Accrued expenses and other liabilities	246	(2,082)
<b>Net cash used in operating activities</b>	<b>(11,634)</b>	<b>(13,952)</b>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(733)	(538)
<b>Net cash used in investing activities</b>	<b>(733)</b>	<b>(538)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options	285	130
Proceeds from issuance of Series D convertible preferred stock, net of issuance costs	6,982	–
Proceeds from issuance of Series E convertible preferred stock, net of issuance costs	80,246	–
Payments made for deferred offering costs	(280)	–
Payments made for deferring financing costs related to issuance of Series D-2 preferred	–	(9)
Other	–	(17)
<b>Net cash provided by financing activities</b>	<b>87,233</b>	<b>104</b>
<b>Net (decrease) increase in cash, cash equivalents and restricted cash</b>	<b>74,866</b>	<b>(14,836)</b>
<b>Cash, cash equivalents and restricted cash at beginning of period</b>	<b>17,487</b>	<b>32,543</b>
<b>Cash, cash equivalents and restricted cash at end of period</b>	<b>\$ 92,353</b>	<b>\$ 18,157</b>
<b>Supplemental Disclosure of Cash Flow Information:</b>		
Purchases of property and equipment in accounts payable and accrued expenses and other liabilities	\$ 152	\$ –
Initial measurement of right-of-use assets and lease liabilities for operating lease	\$ 536	\$ –
Remeasurement of right-of-use assets and lease liabilities for lease modification	\$ 390	\$ –
Right-of-use assets obtained in exchange for operating lease liabilities	\$ 516	\$ –
Deferred financing costs in accounts payable	\$ –	\$ 74
Deferred offering costs in accounts payable	\$ 55	\$ –

*The accompanying notes are an integral part of these unaudited condensed financial statements.*

## 1. Description of Business

Aura Biosciences, Inc. (the “Company” or “Aura”) is a clinical-stage biotechnology company leveraging its novel targeted oncology platform to develop a potential new standard of care across multiple cancer indications, with an initial focus on ocular and urologic oncology. The Company’s proprietary platform enables the targeting of a broad range of solid tumors using Virus-Like Particles, or VLPs, that can be conjugated with drugs or loaded with nucleic acids to create Virus-Like Drug Conjugates, or VDCs. The Company’s VDCs are largely agnostic to tumor type and can recognize a surface marker, known as HSPGs, that are specifically modified and more broadly expressed on many tumors. The Company is developing AU-011, its first VDC product candidate for the first line treatment of primary choroidal melanoma, a rare disease with no drugs approved. The Company is also developing AU-011 for additional ocular oncology indications and in non-muscle invasive bladder cancer. Aura’s team combines expertise in cancer cell biology, ophthalmology, and targeted therapies together with experience in the development and commercialization of orphan products for significant unmet medical needs. Aura’s headquarters are located in Cambridge, Massachusetts.

The Company’s operations to date have consisted primarily of conducting research and development and raising capital.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, the successful development and commercialization of products, fluctuations in operating results and financial risks, need for additional financing or alternative means of financial support or both to fund its current operating plan, protection of proprietary technology and patent risks, compliance with government regulations, dependence on key personnel and collaborative partners, competition, customer demand, management of growth, and the effectiveness of marketing by the Company.

### ***Liquidity and Going Concern***

Through June 30, 2021, the Company has funded its operations primarily with proceeds from the initial closing and additional closings of its convertible preferred stock financings. The Company has incurred recurring losses and negative cash flows from operations since its inception, including net losses of \$14.8 million and \$13.7 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, the Company had cash and cash equivalents of \$92.2 million and an accumulated deficit of \$131.7 million. The Company expects to continue to generate operating losses for the foreseeable future.

As of October 8, 2021, the issuance date of these condensed financial statements, the Company expects that its cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance of the condensed financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

### ***Impact of COVID-19***

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced. Since then, COVID-19 coronavirus has spread globally. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic and the U.S. government- imposed travel restrictions on travel between the United States, Europe and certain other countries. The outbreak and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as certain worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended. The future progression of the pandemic and its effects on the Company’s business and operations are uncertain.

The Company is monitoring the potential impact of COVID-19 on its business and condensed financial statements. The effects of the public health directives and the Company’s work-from-home



policies may negatively impact productivity, disrupt its business, and delay clinical programs and timelines and future clinical trials, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on its ability to conduct business in the ordinary course. These and similar, and perhaps more severe, disruptions in the Company's operations could negatively impact business, results of operations and financial condition, including its ability to obtain financing.

To date, the Company has not incurred impairment losses in the carrying values of its assets as a result of the pandemic and are not aware of any specific related event or circumstance that would require the Company to revise its estimates reflected in the condensed financial statements.

The Company cannot be certain what the overall impact of the COVID-19 pandemic will be on its business and prospects. The extent to which the COVID-19 pandemic will directly or indirectly impact its business, results of operations, financial condition, and liquidity, including planned and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related effects.

## **2. Summary of Significant Accounting Policies**

### ***Basis of Presentation***

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). In management's opinion, the accompanying unaudited condensed financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations, and cash flows.

### ***Unaudited Interim Financial Information***

The accompanying condensed balance sheet as of June 30, 2021, the condensed statements of operations and comprehensive loss, condensed statement of convertible preferred stock and stockholders' deficit and the condensed statements of cash flows for the six months ended June 30, 2020 and 2021 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 June 30, 2021 and the results of its operations and its cash flows for the six months ended June 30, 2020 and 2021. The financial data and other information disclosed in these notes related to the six months ended June 30, 2020 and 2021 are also unaudited. The unaudited condensed results of operations are not necessarily indicative of the operating results that may occur for the full fiscal year. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules, and regulations prescribed by the United States Securities and Exchange Commission ("SEC"). Management believes that the disclosures provided here are adequate to make the information presented not misleading when these unaudited condensed financial statements are read in conjunction with the audited financial statements and notes thereto as of and for the year ended December 31, 2020. The condensed balance sheet data as of December 31, 2020 was derived from the Company's audited financial statements included elsewhere in this prospectus.

### ***Significant Accounting Policies***

The Company's significant accounting policies are disclosed in the audited financial statements for the year ended December 31, 2020, included elsewhere in this prospectus. Since the date of those financial statements, there have been no changes to its significant accounting policies except as noted below.

### **Cash Equivalents**

Cash equivalents are highly liquid investments with an original maturity of 90 days or less at the date of purchase and consist of time deposits and investments in money market funds that invest in U.S. Treasury obligations and government funds with commercial banks and financial institutions.

### **Leases**

Prior to January 1, 2021, the Company accounted for leases in accordance with ASC 840, *Leases*. At lease inception, the Company determined if an arrangement was an operating or capital lease. For operating leases, the Company recognized rent expense, inclusive of rent escalation, holidays and lease incentives, on a straight-line basis over the lease term. The difference between rent expense recorded and the amount paid was charged to deferred rent. The Company presented lease incentives as deferred rent and amortized the incentives as a reduction to rent expense on a straight-line basis over the lease term. The Company classified deferred rent as current and noncurrent liabilities based on the portion of the deferred rent that was scheduled to mature within the proceeding twelve months.

Effective January 1, 2021, the Company accounts for leases in accordance with ASU No. 2016-02, *Leases (Topic 842)* ("ASC 842"). At contract inception, the Company determines if an arrangement is or contains a lease. A lease conveys the right to control the use of an identified asset for a period of time in exchange for consideration. If determined to be or contain a lease, the lease is assessed for classification as either an operating or finance lease at the lease commencement date, defined as the date on which the leased asset is made available for use by the Company, based on the economic characteristics of the lease. For each lease with a term greater than twelve months, the Company records a right-of-use asset and lease liability.

The Company adopted the new leasing standard effective January 1, 2021, using the modified retrospective transition approach which uses the effective date, or January 1, 2021, as the date of initial application. As a result, prior periods are presented in accordance with the previous guidance in ASC 840. ASC 842 provides several optional practical expedients in transition. The Company has elected to apply the package of practical expedients requiring no reassessment of whether any expired or existing contracts are or contain leases, the lease classification of any expired or existing leases, or the capitalization of initial direct costs for any existing leases.

A right-of-use asset represents the economic benefit conveyed to the Company by the right to use the underlying asset over the lease term. A lease liability represents the obligation to make lease payments arising from the lease. The Company elected the practical expedient to not separate lease and non-lease components for all classes of underlying assets and therefore measures each lease payment as the total of the fixed lease and associated non-lease components. Lease liabilities are measured at lease commencement and calculated as the present value of the future lease payments in the contract using the rate implicit in the contract, when available. If an implicit rate is not readily determinable, the Company uses an incremental borrowing rate measured as the rate at which the Company could borrow, on a fully collateralized basis, a commensurate loan in the same currency over a period consistent with the lease term at the commencement date. Right-of-use assets are measured as the lease liability plus initial direct costs and prepaid lease payments, less lease incentives granted by the lessor. The lease term is measured as the noncancelable period in the contract, adjusted for any options to extend or terminate when it is reasonably certain the Company will extend the lease term via such options based on an assessment of economic factors present as of the lease commencement date. The Company elected the practical expedient to not recognize leases with a lease term of twelve months or less.

Components of a lease are split into three categories: lease components, non-lease components, and non-components. The fixed and in-substance fixed contract consideration (including any consideration related to non-components) are allocated, based on the respective relative fair values, to

the lease components and non-lease components. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only.

The Company's operating leases are presented in the condensed balance sheet as operating lease right-of-use assets, classified as noncurrent assets, and operating lease liabilities, classified as current and noncurrent liabilities. Operating lease expense is recognized on a straight-line basis over the lease term. Variable costs associated with a lease, such as maintenance and utilities, are not included in the measurement of the lease liabilities and right-of-use assets but rather are expensed when the events determining the amount of variable consideration to be paid have occurred.

#### **Deferred Offering Costs**

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process preferred stock or common stock 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 convertible preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations. As of June 30, 2021, the Company had deferred offering costs of \$0.3 million.

#### **Derivative Liability**

Derivative financial instruments, as defined in ASC 815, *Accounting for Derivative Financial Instruments and Hedging Activities*, consist of financial instruments or other contracts that contain a notional amount and one or more underlyings (e.g. interest rate, security price or other variable), require no initial net investment and permit net settlement. Derivative financial instruments may be free-standing or embedded in other financial instruments. Further, derivative financial instruments are initially, and subsequently, measured at fair value and recorded as liabilities or, in rare instances, assets.

The Company does not use derivative financial instruments to hedge exposures to cash-flow, market or foreign-currency risks. However, the Company did have a license agreement that included a change of control fee (see Note 12). As required by ASC 815, in certain instances, these instruments are required to be carried as derivative liabilities, at fair value, in the financial statements (see Note 3).

#### **Recently Adopted Accounting Pronouncements**

Upon adoption of ASC 842, the Company recorded lease liabilities and their corresponding right-of-use assets based on the present value of lease payments over the remaining lease term. The adoption of ASC 842 resulted in the recognition of operating lease liabilities of \$0.6 million and operating lease right-of-use assets of \$0.5 million and the derecognition of deferred rent liabilities of \$0.02 million on the Company's balance sheet as of January 1, 2021. The adoption impact relates to the Company's existing operating lease for operating and laboratory space. The adoption of ASC 842 did not have a material impact on the Company's statements of operations and comprehensive loss or statements of cash flows.

### 3. Fair Value of Assets and Liabilities

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of June 30, 2021 and December 31, 2020 (in thousands):

Description	June 30, 2021	Quoted prices active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant other observable inputs (Level 3)
<b>Assets</b>				
Money market funds	\$90,197	\$ 90,197	\$ –	\$ –
Total financial assets	<u>\$90,197</u>	<u>\$ 90,197</u>	<u>\$ –</u>	<u>\$ –</u>
<b>Liability</b>				
Warrant liability	\$ 71	\$ –	\$ –	\$ 71
Derivative liability	52	–	–	52
Total financial liabilities	<u>\$ 123</u>	<u>\$ –</u>	<u>\$ –</u>	<u>\$ 123</u>

Description	December 31, 2020	Quoted prices active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant other observable inputs (Level 3)
<b>Liability</b>				
Warrant liability	\$ 72	\$ –	\$ –	\$ 72
Total financial liabilities	<u>\$ 72</u>	<u>\$ –</u>	<u>\$ –</u>	<u>\$ 72</u>

At June 30, 2021, the Company's cash equivalents include investments in money market funds that invest in U.S. Treasury obligations and government funds, the fair value of which is valued using level 1 inputs. The fair value of the warrant liability was determined based on Level 3 inputs and utilizing the Black-Scholes option pricing model (see Note 10). The fair value of the derivative liability was determined by utilizing assumptions including the probability of payment factors and discount rate used in the most current common stock valuation.

During the six months ended June 30, 2021 and 2020, there were no transfers into or out of Level 3.

The following table set forth a summary of changes in the fair value of the derivative liability, which represents a recurring fair value measurement that is classified within Level 3 of the fair value hierarchy. Changes in fair value are recognized in other (expense) income as "Change in fair value of derivative liability" in the Company's condensed statements of operations and comprehensive loss (in thousands):

<b>Derivative Liability</b>	
Fair value at December 31, 2019	\$ –
Change in fair value	–
Fair value at June 30, 2020	<u>\$ –</u>
Fair value at December 31, 2020	\$ –
Change in fair value	52
Fair value at June 30, 2021	<u>\$52</u>

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The following table set forth a summary of changes in the fair value of the (“Series B Warrants”), which represents a recurring fair value measurement that is classified within Level 3 of the fair value hierarchy. Changes in fair value are recognized in other (expense) income as “Change in fair value of warrant liability” in the Company’s condensed statements of operations and comprehensive loss (in thousands):

<b>Series B Warrants (173,827 warrants)</b>	
Fair value at December 31, 2019	\$75
Change in fair value	—
Fair value at June 30, 2020	<u>\$75</u>
Fair value at December 31, 2020	\$72
Change in fair value	<u>(1)</u>
Fair value at June 30, 2021	<u>\$71</u>

#### **4. Property and Equipment, Net**

Property and equipment, net, consisted of the following (in thousands):

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
Assets under construction	\$ 1,485	\$ 1,154
IT equipment	73	—
Leasehold improvements	13	—
Lab equipment	4,761	4,708
Office furniture	64	64
	<u>\$ 6,396</u>	<u>\$ 5,926</u>
Less—accumulated depreciation	<u>(2,318)</u>	<u>(2,352)</u>
Property and equipment, net	<u>\$ 4,078</u>	<u>\$ 3,574</u>

For the six months ended June 30, 2021 and 2020, depreciation expense was \$0.4 million.

#### **5. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consisted of the following (in thousands):

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
Prepaid insurance	\$ 39	\$ 51
Prepaid research and development expenses	528	915
Prepaid license agreements	49	61
Other	31	16
Prepaid expenses and other current assets	<u>\$ 647</u>	<u>\$ 1,043</u>

#### **6. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following (in thousands):

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
Accrued research and development expenses	\$ 941	\$ 750
Accrued compensation	1,004	1,023
Other	353	277
Accrued expenses and other current liabilities	<u>\$ 2,298</u>	<u>\$ 2,050</u>

## 7. Convertible Preferred Stock

As of June 30, 2021, the Company had 1,701,141 authorized, issued and outstanding shares of Series A convertible preferred stock ("Series A"), 3,298,732 authorized, issued and outstanding shares of Series A-1 convertible preferred stock ("Series A-1"), 4,325,021 authorized shares and 4,324,998 issued and outstanding shares of Series A-2 convertible preferred stock ("Series A-2"), and 22,705,646 authorized shares and 22,531,819 issued and outstanding shares of Series B convertible preferred stock ("Series B"), 58,109,711 authorized, issued and outstanding shares of Series C-1 convertible preferred stock ("Series C-1"), 33,218,192 authorized, issued and outstanding shares of Series C-2 convertible preferred stock ("Series C-2", together with Series C-1, "Series C"), 57,878,742 authorized, issued and outstanding shares of Series D-1 convertible preferred stock ("Series D-1") and 24,598,481 authorized, issued and outstanding shares of Series D-2 convertible preferred stock ("Series D-2", together with Series D-1, "Series D,") 102,671,041 authorized, issued, and outstanding shares of Series E convertible preferred stock ("Series E", and together with the Series D, Series C and Series B, collectively the "Senior Preferred Stock"). All series of convertible preferred stock are collectively referred to as Preferred Stock, each with a par value of \$0.00001 per share.

### **Series D-2 Offering**

On June 25, 2020, the Company entered into the Series D-2 Purchase Agreement ("Series D-2 Agreement") with certain investors to sell up to 24,598,481 shares of Series D-2 stock at a purchase price of \$0.6911 per share. The Series D-2 Agreement provides for two closings, the first on October 1, 2020, and the second upon the achievement or waiver of certain milestone events. The Company sold 14,469,710 shares of Series D-2 stock on October 1, 2020 at the first tranche closing for gross proceeds of \$10.0 million.

On March 5, 2021, the Company completed the second tranche of Series D-2 offering and issued 10,128,771 shares of Series D-2 Stock, \$0.00001 par value per share, at a purchase price of \$0.6911 per share for gross proceeds of \$7.0 million.

Costs incurred in connection with the Series D-2 offering totaled \$0.1 million and were recorded as a reduction to Series D-2 convertible preferred stock. The majority of offering costs were incurred during the year ended December 31, 2020. Offering costs incurred during the six months ended June 30, 2021 was \$0.02 million.

### **Series E Offering**

On March 18, 2021, the Company completed its Series E Stock offering and issued 102,671,041 shares of Series E Stock, \$0.00001 par value per share, at a purchase price of \$0.7839 per share for gross proceeds of \$80.5 million.

Costs incurred in connection with the Series E offering totaled \$0.2 million during the six months June 30, 2021 and were recorded as a reduction to Series E convertible preferred stock.

The rights and privileges of the Company's Preferred Stock are as follows:

### **Voting**

Except as otherwise required by law or by other provisions, holders of the Preferred Stock vote together with the holders of common stock as a single class. Holders of Preferred Stock may cast the number of votes equal to the number of shares of common stock to which such shares of Preferred Stock are convertible into.

### **Dividends**

#### *Series C, D, and E Dividends:*

From and after the date of the issuance of any shares of Series C-1, Series C-2, Series D-1, Series D-2, and Series E, dividends at the annual rate of seven percent (7%) per annum of the original

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share price per share accrue on such shares of Series C-1, Series C-2, Series D-1, Series D-2, and Series E. Dividends accrue from day to day, whether or not declared, and are cumulative, but not compounding. Such dividends are only payable when and if declared by the Board or in the event of a Deemed Liquidation Event (as defined in the amended and restated Certificate of Incorporation). No other dividends may be declared or paid on any other class of stock unless the holders of the shares of Series E then outstanding first receive, or simultaneously receive, their applicable dividend. As of June 30, 2021, \$6.9 million, \$3.0 million, \$5.3 million, \$0.7 million, and \$1.6 million of cumulative dividends on Series C-1, Series C-2, Series D-1, Series D-2, and Series E respectively, are included in the liquidation preference amount indicated on the balance sheet.

### *Series B Dividends:*

From and after the date of the issuance of any shares of Series B, dividends at the annual rate of \$0.0869645 per share accrue on such shares of Series B. Dividends accrue from day to day, whether or not declared, and are cumulative, but not compounding. Such dividends are only payable when and if declared by the Company's Board or in the event of a Deemed Liquidation Event (as defined in the amended and restated Certificate of Incorporation). No other dividends may be declared or paid on any other class of stock unless the holders of the shares of Series B then outstanding first receive, or simultaneously receive, their applicable dividend. As of June 30, 2021, \$10.4 million of cumulative dividends on Series B are included in the liquidation preference amount indicated on the balance sheet.

### *Series A Dividends*

From and after the date of the issuance of Series A, Series A-1, and Series A-2, if the Company declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Company, the dividend payable to the holders of Series A, Series A-1, and Series A-2 convertible preferred stock shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest dividend. No other dividends, or dividends on common stock payable in shares of common stock, may be declared or paid unless the holders of Series A, Series A-1, and Series A-2 then outstanding first receive, or simultaneously receive, their applicable dividend. As of June 30, 2021, no dividends have been declared on the common stock or the convertible preferred stock.

### **Liquidation Rights**

In the event of a Deemed Liquidation Event, as defined in the Company's amended and restated Certificate of Incorporation, the assets of the Company will be distributed first to the holders of Series E. The holders of Series E will receive, in preference to all other stockholders, and amount equal to the sum of the Series E original issue price (equal to the cash price paid per share of \$0.783900), plus unpaid dividends on such shares. Next, the holders of Series D will receive, in preference to all other stockholders other than Series E, an amount equal to the sum of the Series D original issue price, plus unpaid dividends on such shares. Next, the holders of Series C will receive, in preference to all stockholders other than the Series E and D holders, an amount equal to the sum of the Series C original issue price plus unpaid dividends on such shares. Next, the holders of Series B will receive, in preference to the holders of Series A, Series A-1, Series A-2 and common stock, an amount equal to the sum of the Series B original issue price plus unpaid dividends on such shares. Next, the holders of Series A, Series A-1, and Series A-2 will receive, in preference to the holders of common stock, an amount equal to the greater of their applicable liquidation preference or what they would have received had their shares converted into common stock. If the proceeds available are not sufficient to satisfy the full liquidation preference, the entire proceeds are to be distributed pro-rata among the Series E holders in proportion to the full preferential amount the Series E holders are entitled to receive.

### **Conversion**

The Senior Preferred Stock converts into common stock on a one-for-one basis. Each share of Series B, Series C-1, Series C-2, Series D-1, Series D-2, and Series E is convertible into the number of shares of common stock as is determined by dividing the respective original issue price by the

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conversion price in effect at the time of conversion. The Series E conversion price is set at \$0.7839 per share, the Series D-1 and Series D-2 conversion price is set at \$0.6911 per share, the Series C-1 conversion price is set at \$0.5213 per share, the Series C-2 conversion price is set at \$0.36491 per share, and the Series B conversion price is set at \$1.24235 per share; none represents a beneficial conversion feature. Subject to certain exceptions, the Senior Preferred Stock has the benefit of anti-dilution protection on a weighted-average basis in the event that the Company sells stock at less than the applicable conversion price per share.

Each share of Series A and Series A-1 was originally convertible into the number of shares of common stock determined by dividing the respective Series A and Series A-1 original issue price by the conversion price in effect at the time of conversion. The Series A conversion price was originally equal to \$2.00 per share and the Series A-1 conversion price was originally equal to \$2.4847 per share. As Series A-2 was sold at \$1.24235 per share, less than the per share prices of Series A and Series A-1, anti-dilution protections were triggered. Pursuant to the anti-dilution protection terms, on February 24, 2015, the Series A conversion price was reduced from \$2.00 to \$1.8191 per share of common stock and the Series A-1 conversion price was reduced from \$2.4847 to \$2.1898 per share of common stock and, therefore, the Series A conversion ratio was changed from 1:1 to 1:1.099 and the Series A-1 conversion ratio was changed from 1:1 to 1:1.135. The Company evaluated Series A and Series A-1 with the updated conversion ratios and determined that there was no beneficial conversion feature.

Series A-2 converts into common stock on a one-for-one basis. The Series A-2 conversion price is set at \$1.24235 per share and does not represent a beneficial conversion feature.

According to the terms of the Company's amended and restated certificate of incorporation, in the event that the applicable conversion price for any series of Senior Preferred Stock is reduced, then the applicable conversion price for each series of Series A convertible preferred stock shall be uniformly and concurrently reduced.

Each share of Preferred Stock will automatically convert into common stock upon (a) the occurrence of an event, specified by vote or written consent of certain stockholders or (b) the completion of a public stock offering involving a price per share of common stock of not less than \$1.554975 per share, subject to certain adjustments, where such offering results in aggregate gross proceeds to the Company of at least \$50.0 million and the common stock is listed for trading on either the New York Stock Exchange or the Nasdaq Stock Market.

The Company must reserve and keep available out of its authorized but unused capital stock such number of authorized shares of common stock to sufficiently effect the conversion of all outstanding Preferred Stock.

In considering the features of the convertible preferred stock, the Company determined that none of the features, including the conversion features, requires bifurcation during the six months ended June 30, 2021 and 2020.

The conversion ratios for the Series A stock was changed to 13.700 to 1.099, Series A-1 stock was changed to 13.7 to 1.135, and the Series A-2 stock through Series E stock was changed to 13.7 to 1 upon the Company's filing of its amendment to its Amended and Restated Certificate of Incorporation on October 22, 2021 (see Note 16(C)).

## **8. Common Stock**

The Company had 470,183,383 and 232,697,999 authorized shares of common stock, par value \$0.00001 per share, of which 439,068 and 381,123 shares were issued and outstanding as of June 30, 2021 and December 31, 2020, respectively.



## 9. Stock-Based Compensation

On January 15, 2009, the Company's Board adopted the 2009 Long-Term Incentive Stock Option Plan (the "2009 Plan") for the issuance of stock-based compensation to both employees and non-employees. The awards under this plan typically vest over a 24, 36 or 48-month period depending on the option agreement and have a 10-year term. On December 12, 2018, the 2009 Plan expired, and the Company adopted the Aura Biosciences, Inc. 2018 Equity Incentive Plan (the "2018 Plan" and collectively with the 2009 Plan, "the Plans"). No options were modified in conjunction with the expiration of the 2009 Plan. The options granted under the 2009 Plan continue to be outstanding in accordance with their original terms. The 2018 Plan will expire in 2028. Under the 2018 Plan, Aura may grant incentive stock options, non-qualified stock options, restricted and unrestricted stock awards and stock rights.

The Board is authorized to administer the 2018 Plan. In accordance with the provisions of the 2018 Plan, the Board determines the terms of Aura options and other awards issued pursuant thereto, including the following:

- which employees, directors and consultants shall be granted awards;
- the number of shares of common stock subject to options and other awards;
- the exercise price of each option, which generally shall not be less than fair market value of the common stock on the date of grant;
- the termination or cancellation provisions applicable to options;
- the terms and conditions of other awards, including conditions for repurchase, termination or cancellation, issue price and repurchase price; and
- all other terms and conditions upon which each award may be granted in accordance with the 2018 Plan.

In addition, the Board or any committee to which the Board delegates authority may, with the consent of the affected plan participants, re-price or otherwise amend outstanding awards consistent with the terms of the 2018 Plan. On March 18, 2021, the Board approved an increase to the 2018 Plan available option pool of 2,346,228 options. With this increase and the transfer of the available options from the 2009 Plan, there were 910,813 options available for grant under the 2018 Plan at June 30, 2021.

The following table summarizes stock option activity under the 2018 Plan for the six months ended June 30, 2021:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	1,512,129	\$ 3.84	7.77	\$ 1,174
Granted	1,583,854	\$ 5.48		
Exercised	(57,945)	\$ 4.93		
Forfeited	(129,458)	\$ 4.25		
Outstanding at June 30, 2021	<u>2,908,580</u>	<u>\$ 4.66</u>	<u>8.71</u>	<u>\$ 2,435</u>
Exercisable at June 30, 2021	<u>871,790</u>	<u>\$ 3.70</u>	<u>6.64</u>	<u>\$ 1,652</u>

The weighted-average grant date fair value of stock options granted during the six months ended June 30, 2021 was \$3.56 and \$2.74 per share, respectively. The total intrinsic value of options exercised was \$0.01 million and \$0.02 million for the six months ended June 30, 2021 and 2020, respectively.

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The Company has elected to use the Black-Scholes option pricing model to determine the fair value of options granted and generally recognizes the compensation cost of stock-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of stock-based payment awards utilizing the Black-Scholes option pricing model is affected by the estimated fair value of the Company's common stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate, and expected dividends.

The fair value of the stock options issued for the six months ended June 30, 2021 and 2020 was measured with the following weighted-average assumptions:

	<u>June 30, 2021</u>	<u>June 30, 2020</u>
Risk-free interest rate	1.07%	0.58%
Expected term	6.01	6.03
Expected volatility of the underlying stock	74.37%	74.16%
Expected dividend rate	0%	0%

The Company recorded stock-based compensation as follows (in thousands):

	<u>June 30, 2021</u>	<u>June 30, 2020</u>
Research and development	\$ 106	\$ 106
General and administrative	350	260
Total	<u>\$ 456</u>	<u>\$ 366</u>

As of June 30, 2021, there was \$6.7 million of unrecognized compensation expense related to stock options, which is expected to be recognized over a weighted-average period of 2.73 years.

### 10. Series B Warrants

In February 2015 and May 2015, the Company issued warrants to purchase 1,650,098 and 887,536 shares of Series B convertible preferred stock, respectively, at an exercise price of \$1.24235 per share. Each Series B Warrant was immediately exercisable and expires ten years from the original date of issuance. Pursuant to FASB ASC Topic 480, *Distinguishing Liabilities from Equity*, the Series B Warrants were classified as a liability and are re-measured to fair value at each balance sheet date and immediately prior to exercise.

A total of 173,827 of the Series B Warrants remained outstanding at June 30, 2021 and 2020.

The warrants were valued using the Black-Scholes option pricing model. The estimated fair value of the warrants and the significant assumptions used were as follows:

<u>Series B Warrants</u>	<u>June 30, 2021</u>
Series B estimated fair value	\$ 1.12
Volatility	77.74%
Expected term (years)	4.0
Risk free rate	0.46%
Dividend yield	7.00%

During the six months ended June 31, 2020 the change in fair value of the warrant liability was deemed immaterial.

## 11. Compensation

In January 2012, the Company adopted the Aura Biosciences 401(K) Profit Sharing Plan and Trust (the "401(k) Plan") for its employees, which is designed to be qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the 401(k) Plan within statutory and 401(k) Plan limits. The Company makes matching contributions of 100% of the first 6% of employee contributions. The Company made matching contributions in the amount of \$0.1 million for the six months ended June 30, 2021 and 2020.

## 12. Commitments and Contingencies

### Lease Commitments

The Company has historically entered into lease arrangements for its facilities. As of December 31, 2020, the Company had one operating lease for its office and lab facility with required future minimum payments. The lease does not contain any options to renew, terminate, or purchase the underlying asset, and was set to expire on July 31, 2022. As part of its adoption of ASC 842, the Company recorded a right-of-use asset and operating lease liability for this lease as of the effective date.

On March 31, 2021, the Company executed an amendment to the facility lease which included an extension of the expiration date of the original leased premises, the addition of 4,516 square feet of laboratory space with an expected commencement date of May 1, 2021, and the addition of 1,000 square feet of laboratory space with an expected commencement date of June 15, 2021. The lease term for the original and new spaces will expire on July 31, 2023, with an option to renew for an additional 12 months.

Upon the execution of the amendment, which was deemed to be a lease modification, the Company re-evaluated the assumptions made at the original lease commencement date. The Company determined the amendment consists of two separate contracts under ASC 842. One contract is related to the modification of term for the original space, and the other is related to a new right-of-use for the two additional spaces, which are to be accounted for as new leases. The Company remeasured the lease liability and corresponding right-of-use asset for the original space as of the effective date of the amendment to reflect the extended term and recorded in the second quarter of 2021 an additional right-of-use asset and lease liability upon lease commencement of each of the additional space.

The Company also leases office and laboratory equipment for which the related expense is immaterial.

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's leases for the six months ended June 30, 2021 (in thousands):

	<u>Amounts</u>
<b>Lease Cost</b>	
Financing lease costs:	\$ —
Amortization of finance right-of-use assets	11
Interest on finance lease liabilities	—
Operating lease costs	216
Short-term lease costs	—
Variable lease costs	142
Total Lease Costs	<u>\$ 369</u>

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Cash paid for amounts included in the measurement of lease liability—finance leases	\$ 15
Cash paid for amounts included in the measurement of lease liability—operating leases	\$ 214
Weighted-average remaining lease term—finance leases (years)	–
Weighted-average remaining lease term—operating leases (years)	2.08
Weighted-average discount rate—finance leases	7.94%
Weighted-average discount rate—operating leases	3.51%

The following table reconciles the future minimum commitments to the Company's operating lease liabilities at June 30, 2021 (in thousands):

	<u>Operating lease payments</u>
2021 (excluding six months ended June 30, 2021)	\$ 305
2022	625
2023	377
Total lease payments	1,307
Less: present value adjustment	(45)
Total operating lease liabilities at June 30, 2021	<u>1,262</u>
Less: current portion of lease liabilities	<u>601</u>
Lease liabilities, net of current portion	<u>\$ 661</u>

In May 2021, the Company paid in full its finance lease.

### **Laser Purchasing Commitment**

On April 5, 2019, the Company entered into a purchase agreement for equipment with future commitments payable in three installments of €0.2 million each. The first two installments of €0.2 million were paid by the Company in April 2019 and August 2019, respectively. The last installment of €0.2 million will be due upon shipment of the initial order, which is expected to occur in 2021. The Company will receive 20 laser systems upon completion of the final installment payment. Upon receipt of the laser systems, the Company will assess whether the laser systems have an alternative future use and, if so, will capitalize the lasers as a component of fixed assets.

### **License Agreements**

The Company has entered into the following key agreements that relate to the core technology under development:

#### *LI-COR Exclusive License and Supply Agreement*

In January 2014, the Company entered into an Exclusive License and Supply Agreement (the "LI-COR Exclusive License Agreement") with LI-COR, Inc. ("LI-COR") for the license of IRDye 700DX and related licensed patents for the treatment and diagnosis of ocular cancers in humans, and as amended in January 2016, July 2017, April 2018 and April 2019. LI-COR is a related party owning shares of the Company's capital stock. The LI-COR Exclusive License Agreement required a one-time upfront license issue fee of \$0.1 million and requires aggregate milestone payments of up to \$0.2 million upon certain regulatory and development milestones. The Company is also required to pay LI-COR low-single digit royalties on net sales. The term of the LI-COR Exclusive Agreement expires on a country-by-country basis, until the longer of (i) ten years from the first commercial sale of a licensed product in such country and (ii) the last to expire valid claim in such country. The Company recognized zero and \$0.1 million of expenses related to this agreement and related amendments for the six months ended June 30, 2021 and 2020, respectively.

#### *LI-COR Non-Exclusive License and Supply Agreement*

In December 2014, the Company entered into a Non-Exclusive License Agreement ("the 2014 Non- Exclusive Agreement") for LI-COR to supply IRDye 700DX to the Company for the treatment and diagnosis of non-ocular cancers in humans. Under the 2014 Non-Exclusive Agreement, the Company

paid a license issue fee of \$0.03 million on the effective date. The Company must also pay LI-COR a non-refundable, non-creditable fee of \$0.03 million per each licensed product upon pre-IND designation, as defined, of such licensed product. During the term, the Company must pay LI-COR the following royalty on net sales: 1% for sales up to \$0.1 million per year; 1.25% for sales between \$0.1 million and \$0.5 million; 1.75% for sales between \$0.5 million and \$1.0 million; 2.25% for sales between \$1.0 million and \$2.0 million; and 2.75% for sales greater than \$2.0 million. LI-COR receives 10% of all sublicensee income within 30 days of the Company's receipt from the sublicensee. The 2014 Non-Exclusive Agreement also required the Company to make certain payments upon the achievement of specified development and commercial milestones relating to a Phase III clinical trial with NDA submitted for approval to the Food and Drug Administration (the "FDA") (\$0.1 million), first commercial sale of a Licensed product for clinical (non-research) human in vivo use in the United States (\$0.1 million), Marketing Authorization Application ("MAA") approval in the first country in the European Union (\$0.1 million) and MAA (or equivalent) approval in first country outside of the United States or European Union (\$0.1 million).

*Life Technologies Corporation*

In December 2014, the Company entered into a non-exclusive, perpetual license agreement with Life Technologies Corporation ("Life Technologies"), which allows for five licensed products. Under this agreement the Company is required to pay an initial license fee of \$0.1 million for each product. An annual development fee of \$0.1 million is due within a year from the payment of the initial license fee and due annually until the earlier of (i) payment of a commercialization fee or (ii) all development work is terminated. The commercialization fee is a one-time, non-refundable, non-creditable fee of \$0.3 million due upon receipt of approval of a licensed product. In the event of a change of control, there will be a change of control fee of \$0.2 million. The Company recorded a derivative liability due an increased probability of payment assessed this quarter to account for the change of control fee (see Note 3). The derivative liability existed prior to June 2021 but was considered insignificant. During the six months ended June 30, 2021 and 2020, the Company recognized \$0.03 million of expenses related to this agreement.

*National Institute of Health (NIH)-Biologic Materials License Agreement*

In December 2010, the Company entered into a Biologic Materials License Agreement with National Institutes of Health (the "NIH"), for a non-exclusive right to use materials described in Schiller et al., *Virology* 2004 Apr.10, 321(2):205-16, which required a one-time non-refundable license issuance fee of \$0.02 million. No future milestone payments or royalties are due under this agreement.

*National Institute of Health (NIH)-Collaboration Research and Development Agreement*

In July 2011, the Company entered into a Collaboration Research and Development Agreement ("CRADA") with Dr. John Schiller at the NIH, for a period of two years with the rights to an exclusive license to all technology generated within the collaboration. Under the agreement, the Company was required to make annual payments each year to fund the research activities, with the first payment due within 30 days of the effective date and subsequent payments due within 30 days of the anniversary date. This agreement was further amended in 2012, 2013, 2014, 2015, 2016, 2018 and most recently in September of 2020. From 2011-2020, the Company paid an aggregate of \$0.3 million in research collaboration fees, \$0.04 million of which was paid in 2020.

In September 2020, the Company executed the seventh amendment to the CRADA agreement. In this amendment the term of this agreement is extended until September 30, 2022, and the Company must pay \$0.03 million on the tenth anniversary of the CRADA agreement which will occur in September of 2021.

*National Institute of Health (NIH)-Exclusive Patent License Agreement*

In 2013, the Company entered into an exclusive patent license agreement that required the Company to pay a license issue royalty fee of \$0.1 million and reimburse the NIH for any patent expenses incurred. Under the agreement, the Company is required to make low single-digit percentage

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royalty payments based on specified levels of annual net sales of licensed products subject to certain specified reductions. The Company is required to make development and regulatory milestone payments up to \$0.7 million in the aggregate and sales milestone payments up to \$0.6 million in the aggregate. The Company is also required to pay NIH a mid-single to low teen-digit percentage of any sublicensing revenue the Company receives. Additionally, the Company's payment obligations to NIH are subject to an annual minimum royalty payment of low five figures. As of June 30, 2021, the Company has paid NIH approximately \$0.4 million in aggregate milestones under the NIH License Agreement. In addition to milestones under the agreement, the Company reimburses the NIH for any patent filing costs incurred. As of June 30, 2021, the Company has reimbursed the NIH approximately \$0.3 million in aggregate. The Company accrued \$0.02 million in patent licensing reimbursement fees as of June 30, 2021 and December 31, 2020.

In 2015, 2018 and 2019, the Company amended its exclusive patent license to include updates on the status of the commercial development and update/expand the list of licensed patents and patent applications. Each of those amendments required a \$0.03 million payment that the Company paid.

### *Inserm*

In November 2009, the Company entered into an exclusive, royalty-bearing license agreement with Inserm-Transfert of France for use of its patents. The agreement expires on a country by country basis based on the last to expire of any patent encompassed within the scope of the patent rights or 10 years from the date of the first commercial sale by the Company, whichever is later. There are potential milestone payments of €0.5 million (\$0.5 million at December 31, 2020) in the aggregate associated with this agreement. The milestones are as follows: IND Filing (€0.01 million), successful Phase I clinical trial final report (€0.03 million), successful Phase II clinical trial final report (€0.1 million), successful Phase III clinical trial final report (€0.1 million), and approval by the FDA or CHMP for each clinical candidate (€0.3 million). The IND filing milestone of €0.01 million was accrued in 2016 and paid in 2017 by the Company. The milestones for the successful Phase I, II and III clinical trials are based on receiving a final report and achieving the primary endpoints defined in that trial and those milestones have not been achieved as of June 30, 2021. Upon the sublicense by the Company of a product for which royalties are payable under this agreement, royalty payments due Inserm-Transfert would equal 5% of Aura receipts prior to commencement of a proof of principle Phase I clinical trial, 3% of receipts prior to commencement of a proof of principle Phase II clinical trial, and 1.5% of receipts prior to commencement of a proof of principle Phase III clinical trial. If Aura sublicenses the delivery platform for use with multiple drugs, the payment to Inserm-Transfert would be 15% of receipts prior to commencement of Phase I clinical trial, 10% of receipts prior to commencement of Phase II clinical trial, and 6% of receipts prior to commencement of Phase III clinical trial. The non-milestone payments in this agreement are subject to an anti-stacking clause. The Company did not incur any expense in the period ended June 30, 2021 and 2020.

### *Clearside*

In July 2019, the Company entered into a license agreement with Clearside Biomedical, Inc. ("Clearside") for the license of Clearside's Suprachoroidal Microneedle Technology for use in an upcoming clinical trial expected to begin in 2020. Upon execution of the license agreement, the Company paid Clearside an upfront payment of \$0.1 million which was expensed as incurred. Under the Clearside License Agreement, the Company is required to pay milestones up to \$21.0 million in the aggregate to Clearside upon the achievement of specified regulatory and development milestones, and upon the achievement of certain commercial sales milestones. The Company is also required to pay low to mid-single digit royalties on net sales. If the Company sublicenses a product for which royalties are payable, then the Company is required to pay the greater of 20% received or low single digit royalties on net sales. The Company has made no milestone or royalty payments as of June 30, 2021.

The Clearside license agreement expires on a country-by-country basis upon the later of the last to expire patent or ten years from the date of the first commercial sale of a product.

### 13. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is the same as basic net loss per share for the periods presented since the effects of potentially dilutive securities are antidilutive given the net loss of the Company.

The Company has calculated basic and diluted net loss per share for the six months ended June 30, 2021 and 2020 as follows (in thousands, except share and per share data):

	June 30, 2021	June 30, 2020
Numerator:		
Net loss	\$ (14,779)	\$ (13,688)
Less: Accruals of dividends of preferred stock	(5,959)	(3,854)
Net loss attributable to common stockholders—basic and diluted	<u>\$ (20,738)</u>	<u>\$ (17,522)</u>
Denominator:		
Weighted-average common stock outstanding	419,059	355,657
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (49.49)</u>	<u>\$ (49.27)</u>

The following potentially dilutive securities were excluded from the computation of the diluted net loss per share for the periods presented because their effect would have been antidilutive:

	June 30, 2021	June 30, 2020
Convertible preferred stock on an if converted basis	22,550,561	13,260,868
Stock options to purchase common stock	2,908,580	1,474,890
Warrants to purchase preferred stock	12,686	12,686
Total potential dilutive shares	<u>25,471,827</u>	<u>14,748,444</u>

### 14. Income Taxes

The Company estimates an annual effective tax rate of 0% for the year ending December 31, 2021 as the Company incurred losses for the six months ended June 30, 2021 and is forecasting additional losses through the remainder of fiscal year ending December 31, 2021, resulting in an estimated net loss for both financial statement and tax purposes for the year ending December 31, 2021. Therefore, no federal or state income taxes are expected and none have been recorded at this time. Income taxes have been accounted for using the liability method.

Due to the Company's history of losses since inception, there is not enough evidence at this time to support that the Company will generate future income of a sufficient amount and nature to utilize the benefits of its net deferred tax assets. Accordingly, the deferred tax assets have been reduced by a full valuation allowance, since the Company does not currently believe that realization of its deferred tax assets is more likely than not.

As of June 30, 2021, the Company had no unrecognized income tax benefits that would reduce the Company's effective tax rate if recognized.

## **15. Related Parties**

During the six months ended June 30, 2021 and 2020, the Company incurred \$0.04 million and \$0 million in expenses to a legal firm whose partner is also an investor and former officer of the Company. As of June 30, 2021, and 2020, none of these amounts were included in accounts payable.

During the six months ended June 30, 2021 and 2020, the Company incurred \$0.3 million and \$0.1 million in expenses to a stockholder that provided research and development related services. Of these amounts, no amounts were in accrued expenses as of June 30, 2021 and 2020.

During the six months ended June 30, 2021 and 2020, the Company incurred \$0.01 million in expense to a consultant who is also a spouse of an employee at the Company. As of June 30, 2021, and 2020, no amounts were included in accounts payable.

## **16. Subsequent Events**

The Company has evaluated subsequent events from the balance sheet date through the filing date of this Registration Statement on Form S-1, and has identified the following subsequent events:

### **A. Stock-based compensation**

On August 2, 2021, Elisabet de los Pinos, the Company's CEO, exercised options for 3,649 shares of common stock, with an exercise price of \$5.48 per common share.

On October 5, 2021, a holder of the Company's convertible preferred stock exercised options for 2,190 and 1,459 shares of common stock, with exercise prices of \$5.75 and \$5.48 per share of common stock, respectively.

On September 22, 2021, the board of directors approved and granted stock options to purchase 299,626 shares of the common stock under the 2018 Plan. 296,344 of these stock options vest over four years and 3,282 of these stock options vest over one year with exercise prices of \$9.59 per share. The weighted-average fair value of these stock options is \$6.17 per share and the related stock compensation expense of these stock options of \$1.8 million will be recognized over a weighted-average period of 3.97 years.

### **B. Election of Automatic Conversion of Preferred Stock**

On October 7, 2021, the required convertible preferred stockholders authorized the automatic conversion of all shares of convertible preferred stock in an initial public offering, subject to the price per share of the common stock in the Company's sale of shares of common stock to the public in a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least \$75,000,000 of gross proceeds to the Company and such shares being listed on the Nasdaq Stock Market (the "Public Offering"), being at least \$0.94068 (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock), (ii) subject to and effective upon the closing of the Public Offering and (iii) subject to the Public Offering being consummated no later than February 28, 2022.

### **C. Reverse stock split**

On October 22 2021, the Company effected a reverse stock split of the Company's common stock on a 1-for-13.7 basis (the "Reverse Stock Split"). In connection with the Reverse Stock Split, the conversion ratio for the Company's convertible preferred stock was proportionately adjusted such that the common stock issuable upon conversion of such preferred stock was decreased in proportion to the Reverse Stock Split. Accordingly, all common stock share and per share amounts, for all periods



presented in these financial statements have been retroactively adjusted, to reflect this reverse stock split and adjustment of the convertible preferred stock conversion ratios.

**D. 2021 Stock Option and Incentive Plan**

The 2021 Stock Option and Incentive Plan (the "2021 Plan") was adopted by the board of directors on October 7, 2021, approved by the Company's stockholders on October 22, 2021 and will become effective upon the date immediately preceding the date on which the registration statement of which this prospectus is part is declared effective by the SEC. The 2021 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The number of shares initially reserved for issuance under the 2021 Plan was 3,352,166, which will automatically increase on January 1, 2022 and each January 1 thereafter, by 5% of the outstanding number of shares of common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Company's compensation committee. The maximum number of shares of common stock that may be issued in the form of incentive stock options shall not exceed the initial limit, cumulatively increased on January 1, 2022 and on each January 1 thereafter by the lesser of the Annual Increase for such year or 3,352,166 shares of common stock.

**E. 2021 Employee Stock Purchase Plan**

The 2021 Employee Stock Purchase Plan (the "ESPP") was adopted by the board of directors on October 7, 2021, approved by the Company's stockholders on October 22, 2021 and will become effective upon the date immediately preceding the date on which the registration statement of which this prospectus is part is declared effective by the SEC. A total of 335,217 shares of common stock were initially reserved for issuance under this plan, which will automatically increase on January 1, 2022 and each January 1 thereafter through January 1, 2031, by the least of (i) 335,217 shares of common stock, (ii) 1% of the outstanding number of shares of common stock on the immediately preceding December 31 or (iii) such lesser number of shares of common stock as determined by the administrator of the ESPP.

5,400,000 Shares

**aura**

**Common Stock**

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**PROSPECTUS**

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*Joint Book-Running Managers*

**Cowen**

**SVB Leerink**

**Evercore ISI**

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*Lead Manager*

**BTIG**

October 28, 2021

Through and including November 22, 2021 (25 days after the commencement of this offering), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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